DRUG MISUSE

Psychosocial interventions

National Clinical Practice Guideline Number 51

National Collaborating Centre for Mental Health commissioned by the

National Institute for Health & Clinical Excellence

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British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

ISBN: 978-1-85433-468-8

Printed in Great Britain by Alden Press.

Additional material: data CD-ROM created by Pixl8

(www.pixl8.co.uk)

developed by

National Collaborating Centre for Mental Health
Royal College of Psychiatrists' Research and Training Unit
4th Floor, Standon House
21 Mansell Street
London
E1 8AA
www.nccmh.org.uk

commissioned by National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn
London
WCIV 6NA
www.nice.org.uk

published by

The British Psychological Society
St Andrews House
48 Princess Road East
Leicester
LE1 7DR
www.bps.org.uk

an

The Royal College of Psychiatrists 17 Belgrave Square London SW1X 8PG www.rcpsych.ac.uk





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GUIDELINE DEVELOPMENT GROUP MEMBERS

Professor John Strang (Chair, Guideline Development Group)

Professor of Psychiatry of Addictions

Director, National Addiction Centre, Institute of Psychiatry

Honorary Consultant Psychiatrist and Clinical Director of Addictions Division, South London and Maudslev NHS Foundation Trust

Mr Stephen Pilling (Facilitator, Guideline Development Group)

Joint Director, The National Collaborating Centre for Mental Health

Director, Centre for Outcomes, Research and Effectiveness, University College London

Consultant Clinical Psychologist and Deputy Head of Psychology Services, Camden and Islington Mental Health and Social Care Trust

Dr Eliot Ross Albert

Service-user representative

Ms Janet Brotchie

Clinical Psychology Advisor, Quality Team, National Treatment Agency for Substance Misuse

Lead Psychologist, Central and North West London Mental Health NHS Trust Substance Misuse Service

Dr Alex Copello

Clinical Director, Substance Misuse Services and Addictions Research and Development Programme Director, Birmingham and Solihull Mental Health NHS Trust

Senior Lecturer in Clinical Psychology, University of Birmingham

Professor Colin Drummond

Professor of Addiction Psychiatry, St George's Hospital Medical School, University of London

Honorary Consultant Psychiatrist, South West London and St George's NHS Trust

Mr Mark Gilman

North West Regional Manager, National Treatment Agency for Substance Misuse

Ms Sarah Hopkins

Project Manager, The National Collaborating Centre for Mental Health (2006–2007)

Ms Rebecca King

Project Manager, The National Collaborating Centre for Mental Health (2005–2006)

Guideline development group members

Mr Tim Leighton

Head of Professional Education, Training and Research, Clouds Director of Studies, University of Bath Foundation Degree and BSc (Hons) in Addictions Counselling

Mr Ryan Li

Research Assistant, The National Collaborating Centre for Mental Health

Dr Ifigeneia Mavranezouli

Senior Health Economist, The National Collaborating Centre for Mental Health

Mr Peter McDermott

Service-user representative

Dr Nicholas Meader

Systematic Reviewer, The National Collaborating Centre for Mental Health

Ms Peny Retsa

Health Economist, The National Collaborating Centre for Mental Health

Ms Poonam Sood

Research Assistant, The National Collaborating Centre for Mental Health

Ms Sarah Stockton

Information Scientist, The National Collaborating Centre for Mental Health

Mr Andy Stopher

Borough Services Assistant Director (Camden), Substance Misuse Services, Camden and Islington Mental Health and Social Care Trust

Dr Clare Taylor

Editor, The National Collaborating Centre for Mental Health

Mr Ian Wardle

Chief Executive, Lifeline Project, Manchester

Mrs Tina Williams

Carer representative

Chief Executive for The Bridge Project carer service and PANIC user service

Dr Nat Wright

Clinical Director for Substance Misuse, HMP Leeds, Leeds Primary Care Trust

Mr Loukas Xaplanteris

Health Economist, The National Collaborating Centre for Mental Health

ACKNOWLEDGEMENTS

The Guideline Development Group for Drug Misuse: Psychosocial Interventions and the National Collaborating Centre for Mental Health review team would like to thank the following people:

Editorial assistance

Emma Brown

1. EXECUTIVE SUMMARY

KEY PRIORITIES FOR IMPLEMENTATION

The following recommendations have been identified as recommendations for implementation.

Brief interventions

- Opportunistic brief interventions focused on motivation should be offered to people in limited contact with drug services (for example, those attending a needle and syringe exchange or primary care settings) if concerns about drug misuse are identified by the service user or staff member. These interventions should:
 - normally consist of two sessions each lasting 10-45 minutes
 - explore ambivalence about drug use and possible treatment, with the aim of increasing motivation to change behaviour, and provide non-judgemental feedback. See Section 7.2.8.

Self-help

• Staff should routinely provide people who misuse drugs with information about self-help groups. These groups should normally be based on 12-step principles; for example, Narcotics Anonymous and Cocaine Anonymous. See Section 8.6.4.

Contingency management

- Drug services should introduce contingency management programmes as part of the phased implementation programme led by the National Treatment Agency for Substance Misuse (NTA) to reduce illicit drug use and/or promote engagement with services for people receiving methadone maintenance treatment. See Section 8.4.6.
- Contingency management aimed at reducing illicit drug use for people receiving methadone maintenance treatment or who primarily misuse stimulants should be based on the following principles.
 - The programme should offer incentives (usually vouchers that can be exchanged for goods or services of the service user's choice or privileges such as take-home methadone doses) contingent on each presentation of a drugnegative test (for example, free from cocaine or non-prescribed opioids).

- The frequency of screening should be set at three tests per week for the first 3 weeks, two tests per week for the next 3 weeks, and one per week thereafter until stability is achieved.
- If vouchers are used, they should have monetary values that start in the region of £2 and increase with each additional, continuous period of abstinence.
- Urinalysis should be the preferred method of testing but oral fluid tests may be considered as an alternative.

See Sections 8.3.5 and 8.4.6.

Contingency management to improve physical healthcare

- For all people at risk of physical health problems (including transmittable diseases) resulting from their drug misuse, material incentives (for example, shopping vouchers of up to £10 in value) should be considered to encourage harm reduction. Incentives should be offered on a one-off basis or over a limited duration, contingent on concordance with or completion of each intervention, in particular for:
 - hepatitis B/C and HIV testing
 - hepatitis B immunisation
 - tuberculosis testing.

See Section 7.3.5.

Implementing contingency management

- Drug services should ensure that as part of the introduction of contingency management, staff are trained and competent in appropriate near-patient testing methods and in the delivery of contingency management.
- Contingency management should be introduced to drug services in the phased implementation programme led by the NTA, in which staff training and the development of service delivery systems are carefully evaluated. The outcome of this evaluation should be used to inform the full-scale implementation of contingency management.

See Section 8.3.5 and 8.4.6.

1.1 GENERAL CONSIDERATIONS

1.1.1 Care of people who misuse drugs

1.1.1.1 To enable people who misuse drugs to make informed decisions about their treatment and care, staff should explain options for abstinence-oriented, maintenance-oriented and harm-reduction interventions at the person's initial contact with services and at subsequent formal reviews.

- 1.1.1.2 Staff should discuss with people who misuse drugs whether to involve their families and carers in their assessment and treatment plans. However, staff should ensure that the service user's right to confidentiality is respected.
- 1.1.1.3 In order to reduce loss of contact when people who misuse drugs transfer between services, staff should ensure that there are clear and agreed plans to facilitate effective transfer.
- 1.1.1.4 All interventions for people who misuse drugs should be delivered by staff who are competent in delivering the intervention and who receive appropriate supervision.
- 1.1.1.5 People who misuse drugs should be given the same care, respect and privacy as any other person.

1.1.2 Supporting families and carers

- 1.1.2.1 Staff should ask families and carers about, and discuss concerns regarding, the impact of drug misuse on themselves and other family members, including children. Staff should also:
 - offer family members and carers an assessment of their personal, social and mental health needs
 - provide verbal and written information and advice on the impact of drug misuse on service users, families and carers.
- 1.1.2.2 Where the needs of families and carers of people who misuse drugs have been identified, staff should:
 - offer guided self-help, typically consisting of a single session with the provision of written material
 - provide information about, and facilitate contact with, support groups, such as self-help groups specifically focused on addressing families' and carers' needs.
- 1.1.2.3 Where the families of people who misuse drugs have not benefited, or are not likely to benefit, from guided self-help and/or support groups and continue to have significant problems, staff should consider offering individual family meetings. These should:
 - provide information and education about drug misuse
 - help to identify sources of stress related to drug misuse
 - explore and promote effective coping behaviours
 - normally consist of at least five weekly sessions.

1.2 IDENTIFICATION AND ASSESSMENT OF DRUG MISUSE

1.2.1 Asking questions about drug misuse

1.2.1.1 Staff in mental health and criminal justice settings (in which drug misuse is known to be prevalent) should ask service users routinely about recent

legal and illicit drug use. The questions should include whether they have used drugs and, if so:

- of what type and method of administration
- in what quantity
- how frequently.
- 1.2.1.2 In settings such as primary care, general hospitals and emergency departments, staff should consider asking people about recent drug use if they present with symptoms that suggest the possibility of drug misuse, for example:
 - acute chest pain in a young person
 - acute psychosis
 - mood and sleep disorders.

1.2.2 Assessment

- 1.2.2.1 When making an assessment and developing and agreeing a care plan, staff should consider the service user's:
 - medical, psychological, social and occupational needs
 - history of drug use
 - experience of previous treatment, if any
 - goals in relation to his or her drug use
 - treatment preferences.
- 1.2.2.2 Staff who are responsible for the delivery and monitoring of the agreed care plan should:
 - establish and sustain a respectful and supportive relationship with the service user
 - help the service user to identify situations or states when he or she is vulnerable to drug misuse and to explore alternative coping strategies
 - ensure that all service users have full access to a wide range of services
 - ensure that maintaining the service user's engagement with services remains a major focus of the care plan
 - maintain effective collaboration with other care providers.
- 1.2.2.3 Healthcare professionals should use biological testing (for example, of urine or oral fluid samples) as part of a comprehensive assessment of drug use, but they should not rely on it as the sole method of diagnosis and assessment.

1.3 BRIEF INTERVENTIONS AND SELF-HELP

1.3.1 Brief interventions

1.3.1.1 During routine contacts and opportunistically (for example, at needle and syringe exchanges), staff should provide information and advice to all people who misuse drugs about reducing exposure to blood-borne viruses.

- This should include advice on reducing sexual and injection risk behaviours. Staff should consider offering testing for blood-borne viruses.
- 1.3.1.2 Group-based psychoeducational interventions that give information about reducing exposure to blood-borne viruses and/or about reducing sexual and injection risk behaviours for people who misuse drugs should not be routinely provided.
- 1.3.1.3 Opportunistic brief interventions focused on motivation should be offered to people in limited contact with drug services (for example, those attending a needle and syringe exchange or primary care settings) if concerns about drug misuse are identified by the service user or staff member. These interventions should:
 - normally consist of two sessions each lasting 10–45 minutes
 - explore ambivalence about drug use and possible treatment, with the aim of increasing motivation to change behaviour, and provide nonjudgemental feedback.
- 1.3.1.4 Opportunistic brief interventions focused on motivation should be offered to people not in contact with drug services (for example, in primary or secondary care settings, occupational health or tertiary education) if concerns about drug misuse are identified by the person or staff member. These interventions should:
 - normally consist of two sessions each lasting 10–45 minutes
 - explore ambivalence about drug use and possible treatment, with the aim
 of increasing motivation to change behaviour, and provide nonjudgemental feedback.

1.3.2 Self-help

- 1.3.2.1 Staff should routinely provide people who misuse drugs with information about self-help groups. These groups should normally be based on 12-step principles; for example, Narcotics Anonymous and Cocaine Anonymous.
- 1.3.2.2 If a person who misuses drugs has expressed an interest in attending a 12-step self-help group, staff should consider facilitating the person's initial contact with the group, for example by making the appointment, arranging transport, accompanying him or her to the first session and dealing with any concerns.

1.4 FORMAL PSYCHOSOCIAL INTERVENTIONS

1.4.1 Contingency management

1.4.1.1 Drug services should introduce contingency management programmes – as part of the phased implementation programme led by the NTA – to reduce illicit drug use and/or promote engagement with services for people receiving methadone maintenance treatment.

- 1.4.1.2 Drug services should introduce contingency management programmes as part of the phased implementation programme led by the NTA to reduce illicit drug use, promote abstinence and/or promote engagement with services for people who primarily misuse stimulants.
- 1.4.1.3 Staff delivering contingency management programmes should ensure that:
 - the target is agreed in collaboration with the service user
 - the incentives are provided in a timely and consistent manner
 - the service user fully understands the relationship between the treatment goal and the incentive schedule
 - the incentive is perceived to be reinforcing and supports a healthy/drug-free lifestyle.
- 1.4.1.4 Contingency management aimed at reducing illicit drug use for people receiving methadone maintenance treatment or who primarily misuse stimulants should be based on the following principles.
 - The programme should offer incentives (usually vouchers that can be exchanged for goods or services of the service user's choice, or privileges such as take-home methadone doses) contingent on each presentation of a drug-negative test (for example, free from cocaine or non-prescribed opioids).
 - If vouchers are used, they should have monetary values that start in the region of £2 and increase with each additional, continuous period of abstinence.
 - The frequency of screening should be set at three tests per week for the first 3 weeks, two tests per week for the next 3 weeks, and one per week thereafter until stability is achieved.
 - Urinalysis should be the preferred method of testing but oral fluid tests may be considered as an alternative.

1.4.2 Contingency management to improve physical healthcare

- 1.4.2.1 For people at risk of physical health problems (including transmittable diseases) resulting from their drug misuse, material incentives (for example, shopping vouchers of up to £10 in value) should be considered to encourage harm reduction. Incentives should be offered on a one-off basis or over a limited duration, contingent on concordance with or completion of each intervention, in particular for:
 - hepatitis B/C and HIV testing
 - hepatitis B immunisation
 - tuberculosis testing.

1.4.3 Implementing contingency management

1.4.3.1 Drug services should ensure that as part of the introduction of contingency management, staff are trained and competent in appropriate near-patient testing methods and in the delivery of contingency management.

1.4.3.2 Contingency management should be introduced to drug services in the phased implementation programme led by the NTA, in which staff training and the development of service delivery systems are carefully evaluated. The outcome of this evaluation should be used to inform the full-scale implementation of contingency management.

1.4.4 Behavioural couples therapy

- 1.4.4.1 Behavioural couples therapy should be considered for people who are in close contact with a non-drug-misusing partner and who present for treatment of stimulant or opioid misuse (including those who continue to use illicit drugs while receiving opioid maintenance treatment or after completing opioid detoxification). The intervention should:
 - focus on the service user's drug misuse
 - consist of at least 12 weekly sessions.

1.4.5 Interventions to improve concordance with naltrexone treatment

- 1.4.5.1 For people receiving naltrexone maintenance treatment to help prevent relapse to opioid dependence, staff should consider offering:
 - contingency management to all service users (based on the principles described in recommendations 1.4.1.3 and 1.4.1.4)
 - behavioural couples therapy or behavioural family interventions to service users in close contact with a non-drug-misusing family member, carer or partner (based on the principles described in recommendation 1.4.3.1 for behavioural couples therapy).

1.4.6 Cognitive behavioural therapy and psychodynamic therapy

- 1.4.6.1 Cognitive behavioural therapy and psychodynamic therapy focused on the treatment of drug misuse should not be offered routinely to people presenting for treatment of cannabis or stimulant misuse or those receiving opioid maintenance treatment.
- 1.4.6.2 Evidence-based psychological treatments (in particular, cognitive behavioural therapy) should be considered for the treatment of comorbid depression and anxiety disorders in line with existing NICE guidance for people who misuse cannabis or stimulants, and for those who have achieved abstinence or are stabilised on opioid maintenance treatment.

1.5 RESIDENTIAL, PRISON AND INPATIENT CARE

1.5.1 Inpatient and residential settings

1.5.1.1 The same range of psychosocial interventions should be available in inpatient and residential settings as in community settings. These should

- normally include contingency management, behavioural couples therapy and cognitive behavioural therapy. Services should encourage and facilitate participation in self-help groups.
- 1.5.1.2 Residential treatment may be considered for people who are seeking abstinence and who have significant comorbid physical, mental health or social (for example, housing) problems. The person should have completed a residential or inpatient detoxification programme and have not benefited from previous community-based psychosocial treatment.
- 1.5.1.3 People who have relapsed to opioid use during or after treatment in an inpatient or residential setting should be offered an urgent assessment. Offering prompt access to alternative community, residential or inpatient support, including maintenance treatment, should be considered.

1.5.2 Criminal justice system

- 1.5.2.1 For people who misuse drugs, access to and choice of treatment should be the same whether they participate in treatment voluntarily or are legally required to do so.
- 1.5.2.2 For people in prison who have drug misuse problems, treatment options should be comparable to those available in the community. Healthcare professionals should take into account additional considerations specific to the prison setting, which include:
 - the length of sentence or remand period, and the possibility of unplanned release
 - risks of self-harm, death or post-release overdose.
- 1.5.2.3 People in prison who have significant drug misuse problems may be considered for a therapeutic community developed for the specific purpose of treating drug misuse within the prison environment.
- 1.5.2.4 For people who have made an informed decision to remain abstinent after release from prison, residential treatment should be considered as part of an overall care plan.

1.6 RESEARCH RECOMMENDATIONS

1.6.1 Implementation of contingency management

Which methods of implementing contingency management (including delivering and stopping incentives) and which settings (including legally coerced community-based and residential) – compared with one another and with standard care – are associated with the longest periods of continued abstinence and reduced drug misuse, and with maintenance of abstinence/reduction of drug misuse at follow-up?

Why this is important

Although the efficacy of contingency management for drug misuse has been extensively investigated, there is a lack of large-scale and well-conducted

Executive summary

implementation studies. The implementation of contingency management programmes in the UK would be aided by research assessing specific components of the programme.

1.6.2 Testing within contingency management programmes

For people who misuse drugs and who are participating in contingency management, which method of testing – urinalysis, sweat analysis or oral fluid analysis – is most sensitive, specific, cost effective and acceptable to service users?

Why this is important

There is a lack of data comparing the sensitivity and specificity, cost effectiveness and acceptability to service users of these methods of testing. Identifying drug use during treatment is an important aspect of contingency management; identifying which testing methods are the most effective is important for health and social care services intending to implement contingency management programmes.

1.6.3 Psychosocial interventions within needle and syringe exchange programmes

For people who inject drugs, do needle and syringe exchange programmes with a greater psychosocial content reduce injection and sexual risk behaviours and rates of seroprevalence of blood-borne virus infection more than programmes with minimal psychosocial content? Examples of greater psychosocial content include distribution of syringes and needles by staff and/or provision of psychoeducation on reducing the risk of blood-borne viruses. Examples of minimal psychosocial content include machine dispensing of syringes and needles and provision of minimal or no information on reducing blood-borne virus risk.

Why this is important

There is extensive literature assessing whether needle and syringe exchange programmes reduce injection and sexual risk behaviours and HIV seroprevalence rates. However, there is very little research that seeks to distinguish the impact of the provision of sterile needles from that of the psychosocial interventions often offered within such programmes. Psychosocial contact and interventions require substantial resources; therefore it is important to assess whether these additional elements are clinically and cost effective.

1.6.4 Residential treatment

Is residential treatment associated with higher rates of abstinence or reduction in drug misuse than community-based care?

Why this is important

There have been some studies comparing residential treatment with community-based treatment. However, these studies are often based on small sample sizes, lack methodological quality and have produced inconsistent results. Residential treatment requires significantly more resources than community-based treatment, so it is important to assess whether residential treatment is more effective.

2. INTRODUCTION

This guideline has been developed to advise on psychosocial interventions for drug misuse. The guideline recommendations have been developed by a multidisciplinary team of healthcare professionals, service users, a carer and guideline methodologists after careful consideration of the best available evidence. It is intended that the guideline will be useful to clinicians and service commissioners in providing and planning high-quality care for people who misuse drugs while also emphasising the importance of the experience of care for people who misuse drugs and their carers (see Appendix 1 for more details on the scope of the guideline).

Although the evidence base is rapidly expanding, there are a number of major gaps, and future revisions of this guideline will incorporate new scientific evidence as it develops. The guideline makes a number of research recommendations specifically to address gaps in the evidence base. In the meantime, it is hoped that the guideline will assist clinicians, people who misuse drugs and their carers by identifying the merits of particular treatment approaches where the evidence from research and clinical experience exists.

2.1 NATIONAL GUIDELINES

2.1.1 What are clinical practice guidelines?

Clinical practice guidelines are 'systematically developed statements that assist clinicians and patients in making decisions about appropriate treatment for specific conditions' (Mann, 1996). They are derived from the best available research evidence, using predetermined and systematic methods to identify and evaluate the evidence relating to the specific condition in question. Where evidence is lacking, the guidelines incorporate statements and recommendations based upon the consensus statements developed by the Guideline Development Group (GDG).

Clinical guidelines are intended to improve the process and outcomes of health-care in a number of different ways. They can:

- provide up-to-date evidence-based recommendations for the management of conditions and disorders by healthcare professionals
- be used as the basis to set standards to assess the practice of healthcare professionals
- form the basis for education and training of healthcare professionals
- assist patients and carers in making informed decisions about their treatment and care
- improve communication between healthcare professionals, patients and carers
- help identify priority areas for further research.

2.1.2 Uses and limitations of clinical guidelines

Guidelines are not a substitute for professional knowledge and clinical judgement. They can be limited in their usefulness and applicability by a number of different factors: the availability of high-quality research evidence, the quality of the methodology used in the development of the guideline, the generalisability of research findings and the uniqueness of individuals who misuse drugs.

Although the quality of research in this field is variable, the methodology used here reflects current international understanding on the appropriate practice for guideline development (AGREE: Appraisal of Guidelines for Research and Evaluation Instrument; www.agreecollaboration.org), ensuring the collection and selection of the best research evidence available and the systematic generation of treatment recommendations applicable to the majority of service users and situations. However, there will always be some people for whom clinical guideline recommendations are not appropriate and situations in which the recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of healthcare professionals to make appropriate decisions in light of the service user's circumstances, in consultation with the person who misuses drugs or carer.

In addition to the clinical evidence, cost-effectiveness information, where available, is taken into account in the generation of statements and recommendations of the clinical guidelines. While national guidelines are concerned with clinical and cost effectiveness, issues of affordability and implementation costs are to be determined by the National Health Service (NHS).

In using guidelines, it is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. In addition, of particular relevance in mental health, evidence-based treatments are often delivered within the context of an overall treatment programme including a range of activities, the purpose of which may be to help engage the person and to provide an appropriate context for the delivery of specific interventions. It is important to maintain and enhance the service context in which these interventions are delivered; otherwise the specific benefits of effective interventions will be lost. Indeed, the importance of organising care in order to support and encourage a good therapeutic relationship is at times as important as the specific treatments offered.

2.1.3 Why develop national guidelines?

The National Institute for Health and Clinical Excellence (NICE) was established as a Special Health Authority for England and Wales in 1999, with a remit to provide a single source of authoritative and reliable guidance for patients, professionals and the public. NICE guidance aims to improve standards of care, to diminish unacceptable variations in the provision and quality of care across the NHS and to ensure that the health service is patient centred. All guidance is developed in a transparent and collaborative manner using the best available evidence and involving all relevant stakeholders.

Introduction

NICE generates guidance in a number of different ways, three of which are relevant here. First, national guidance is produced by the Technology Appraisal Committee to give robust advice about a particular treatment, intervention, procedure or other health technology. Second, NICE commissions public health intervention guidance focused on types of activity (interventions) that help to reduce people's risk of developing a disease or condition or help to promote or maintain a healthy lifestyle. Third, NICE commissions the production of national clinical practice guidelines focused upon the overall treatment and management of a specific condition. To enable this latter development, NICE has established seven National Collaborating Centres in conjunction with a range of professional organisations involved in healthcare.

2.1.4 The National Collaborating Centre for Mental Health

This guideline has been commissioned by NICE and developed within the National Collaborating Centre for Mental Health (NCCMH). The NCCMH is a collaboration of the professional organisations involved in the field of mental health, national patient and carer organisations, a number of academic institutions and NICE. The NCCMH is funded by NICE and is led by a partnership between the Royal College of Psychiatrists' Research and Training Unit and the British Psychological Society's equivalent unit (Centre for Outcomes Research and Effectiveness).

2.1.5 From national guidelines to local protocols

Once a national guideline has been published and disseminated, local healthcare groups will be expected to produce a plan and identify resources for implementation, along with appropriate timetables. Subsequently, a multidisciplinary group involving commissioners of healthcare, primary care and specialist mental health professionals, patients and carers should undertake the translation of the implementation plan into local protocols taking into account both the recommendations set out in this guideline and the priorities set in the National Service Framework (NSF) for Mental Health and related documentation. The nature and pace of the local plan will reflect local healthcare needs and the nature of existing services; full implementation may take a considerable time, especially where substantial training needs are identified.

2.1.6 Auditing the implementation of guidelines

This guideline identifies key areas of clinical practice and service delivery for local and national audit. Although the generation of audit standards is an important and necessary step in the implementation of this guidance, a more broadly based implementation strategy will be developed. Nevertheless, it should be noted that the Healthcare

Commission will monitor the extent to which Primary Care Trusts, trusts responsible for mental health and social care and Health Authorities have implemented these guidelines.

2.2 THE NATIONAL PSYCHOSOCIAL INTERVENTIONS FOR DRUG MISUSE GUIDELINE

2.2.1 Who has developed this guideline?

The GDG was convened by the NCCMH and supported by funding from NICE. The GDG included two service users and a carer, and professionals from psychiatry, clinical psychology, general practice, the prison service, the National Treatment Agency for Substance Misuse (NTA) and the private and voluntary sectors.

Staff from the NCCMH provided leadership and support throughout the process of guideline development, undertaking systematic searches, information retrieval, appraisal and systematic review of the evidence. Members of the GDG received training in the process of guideline development from NCCMH staff, and the service users and carer received training and support from the NICE Patient and Public Involvement Programme. The NICE Guidelines Technical Advisor provided advice and assistance regarding aspects of the guideline development process.

All GDG members made formal declarations of interest at the outset, which were updated at every GDG meeting. The GDG met a total of nine times throughout the process of guideline development. It met as a whole, but key topics were led by a national expert in the relevant topic. The GDG was supported by the NCCMH technical team, with additional expert advice from special advisors where needed. The group oversaw the production and synthesis of research evidence before presentation. All statements and recommendations in this guideline have been generated and agreed by the whole GDG.

2.2.2 For whom is this guideline intended?

This guideline will be relevant for adults and young people who misuse drugs.

The guideline covers the care provided by primary, community, secondary, tertiary and other healthcare professionals who have direct contact with, and make decisions concerning the care of, adults and young people who misuse drugs.

The guideline will also be relevant to the work, but will not cover the practice, of those in:

- occupational health services
- social services
- the independent sector.

The experience of drug misuse can affect the whole family and often the community. The guideline recognises the role of both in the treatment and support of people who misuse drugs.

2.2.3 Specific aims of this guideline

The guideline makes recommendations for psychosocial interventions for drug misuse. It aims to:

- evaluate the role of specific psychosocial interventions in the treatment of drug misuse
- evaluate the role of specific psychosocial interventions in combination with pharmacological interventions in the treatment of drug misuse
- integrate the above to provide best-practice advice on the care of individuals throughout the course of their drug misuse
- promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the NHS in England and Wales.

2.2.4 The structure of this guideline

The guideline is divided into chapters, each covering a set of related topics. The first three chapters provide a summary of the clinical practice and research recommendations, a general introduction to guidelines and an introduction to the drug misuse topic. The fourth chapter provides a summary of the methods used to develop the recommendations and in Chapter 5 there is an overview of service user involvement and experience and impact of drug misuse on carers. Chapters 6 to 9 provide the evidence that underpins the recommendations.

Each evidence chapter begins with a general introduction to the topic that sets the recommendations in context. Depending on the nature of the evidence, narrative reviews or meta-analyses were conducted. Therefore, the structure of the chapters varies accordingly. Where appropriate, details about current practice, the evidence base and any research limitations are provided. Where meta-analyses were conducted, information is given about both the interventions included and the studies considered for review. Clinical summaries are then used to summarise the evidence presented. Finally, recommendations related to each topic are presented at the end of each relevant section of a chapter. On the CD-ROM, full details about the included studies can be found in Appendix 14. Where meta-analyses were conducted, the data are presented using forest plots in Appendix 15 (see Text Box 1 for details).

Text Box 1: Appendices on CD-ROM

Content	Appendix
Reviewed studies	Appendix 14
Forest plots	Appendix 15
Evidence profile tables	Appendix 16

3. INTRODUCTION TO DRUG MISUSE

3.1 DRUG MISUSE

This guideline is concerned with psychosocial treatment of the misuse of opioids, stimulants and cannabis. In the UK, it has been estimated that around 4 million people use illicit drugs each year, with cannabis by far the most commonly used, followed by cocaine and ecstasy (Roe & Man, 2006). Opioid misuse occurs on a smaller scale but is associated with much greater rates of harm than either cocaine or cannabis.

The term 'opioids' refers to a class of psychoactive substances derived from the poppy plant (including opium, morphine and codeine), as well as semi-synthetic forms (including heroin) and synthetic compounds (including methadone and buprenorphine) with similar properties (World Health Organization [WHO], 2006). Illicit use of opioids generally involves injecting, or inhaling the fumes produced by heating the drug. The term 'opiate' refers strictly to the subset of opioids that are naturally occurring or semi-synthetic, and therefore includes heroin and morphine but excludes methadone and buprenorphine.

Stimulants refer broadly to any substance that activates, enhances or increases neural activity (WHO, 2006). Illicit stimulants include cocaine, crack cocaine and amphetamines. Cocaine is one of the most commonly misused illicit stimulants in the UK (Roe & Man, 2006). It is extracted from the leaf of the coca plant and generally sniffed in powder form. Crack cocaine is usually smoked but sometimes injected. Amphetamines are a group of synthetic substances with different chemical structures but broadly similar stimulant properties to cocaine, and include dexamphetamine sulphate (a prescription drug licensed for the treatment of narcolepsy and attention-deficit hyperactivity disorder but which has misuse potential) and methamphetamine.

Cannabis is a generic term denoting the various preparations of the cannabis sativa plant, including cannabis leaves (the most common form, which is smoked), hashish resin and the rarely used cannabis oil. Tetrahydrocannabinol is the key constituent of cannabis that produces the psychoactive effect sought by most users, and the different forms of cannabis vary in their tetrahydrocannabinol content (WHO, 2006). Cannabis is the most commonly used illicit drug in the UK (Roe & Man, 2006).

Definitions

Drug misuse is defined as the use of a substance for a purpose not consistent with legal or medical guidelines (WHO, 2006). It has a negative impact on health or functioning and may take the form of drug dependence, or be part of a wider spectrum of problematic or harmful behaviour (DH, 2006b). In the UK, the Advisory Council on the Misuse of Drugs (ACMD) characterises problem drug use as a condition that may cause an individual to experience social, psychological, physical or legal problems related to intoxication and/or regular excessive consumption, and/or dependence (ACMD, 1998).

In this guideline, dependence is defined as a strong desire or sense of compulsion to take a substance, a difficulty in controlling its use, the presence of a physiological withdrawal state, tolerance of the use of the drug, neglect of alternative pleasures and interests and persistent use of the drug, despite harm to oneself and others (WHO, 2006). Dependence is diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) when three or more of the following criteria are present in a 12-month period: tolerance; withdrawal; increasing use over time; persistent or unsuccessful attempts to reduce use; preoccupation or excessive time spent on use or recovery from use; negative impact on social, occupational or recreational activity; and continued use despite evidence of its causing psychological or physical problems (American Psychiatric Association [APA], 1994).

The diagnosis of dependence is clearest with opioids. The WHO states that:

'opioid dependence develops after a period of regular use of opioids, with the time required varying according to the quantity, frequency and route of administration, as well as factors of individual vulnerability and the context in which drug use occurs. Opioid dependence is not just a heavy use of the drug but a complex health connotation that has social, psychological and biological determinants and consequences, including changes in the brain. It is not a weakness of character or will.' (WHO, 2006)

However, dependence, as characterised by the above definition, can also occur with stimulants and cannabis.

Repeated use of a drug can lead to the development of tolerance in which increased doses of the drug are required to produce the same effect. Tolerance develops to opioids, stimulants and cannabis. Cessation of use leads to reduced tolerance and this may present significant risks for individuals who return to drug doses at a level to which they had previously developed tolerance. This can result in accidental overdoses and, in the case of opioid misuse, could lead to respiratory depression and death.

Withdrawal syndromes have clearly been identified after cessation or reduction of opioid and stimulant use. DSM-IV criteria for a withdrawal disorder include the development of a substance-specific syndrome due to cessation or reduction in use; the syndrome causing clinically significant distress; and symptoms not due to a general medical condition or better explained by another mental disorder (APA, 1994). While withdrawal effects have been associated with cessation of heavy cannabis use, their clinical significance is uncertain at present (Budney *et al.*, 2004).

Opioids, stimulants and cannabis also produce intoxication, that is, disturbances in psychophysiological functions and responses, including consciousness, cognition and behaviour, following administration (WHO, 2006). These are described in greater detail in Section 3.5.

People who misuse drugs may present with a range of health and social problems other than dependence, which may include (particularly with opioid users):

• physical health problems (for example, thrombosis, abscesses, overdose, hepatitis B and C, HIV, and respiratory and cardiac problems)

- mental health problems (for example, depression, anxiety, paranoia and suicidal thoughts)
- social difficulties (for example, relationship problems, financial difficulties, unemployment and homelessness)
- criminal justice problems.

Many people who misuse drugs use a range of substances concurrently and regularly (known as polydrug misuse). The use of opioids alongside cocaine or crack cocaine is common, with the National Drug Treatment Monitoring System (NDTMS), which collects, collates and analyses information from those involved in the drug treatment system, reporting an increase in the use of both drugs, from 18% of those presenting for drug treatment in 1998 to 24% in 2001 (NTA, 2005). Alcohol misuse is also common in all types of people who misuse drugs; data from the National Treatment Outcomes Research Study (NTORS) on drug misuse suggested that 22% of participants also drank alcohol frequently, 17% drank extremely heavily and 8% drank an excessive amount on a daily basis (Gossop *et al.*, 2000a). People who misuse opioids in particular may often take a cocktail of substances, including alcohol, cannabis and prescribed drugs such as benzodiazepines, which can have especially dangerous effects in comparison with one of the drugs taken individually.

Drug dependence is associated with a high incidence of criminal activity, with associated costs to the criminal justice system in the UK estimated as reaching £1 billion per annum in 1996 (United Kingdom Anti-Drugs Coordinating Unit, 1998). For example, more than 17,000 offences were reported by an NTORS cohort of 753 participants in a 90-day period before entering treatment (Gossop et al., 2000b). Notably, most of the offences were committed by a small proportion of the cohort (10% of participants accounted for 76% of the crimes). Illicit drug use is also much more common among known offenders in the UK than among cohorts of comparable age drawn from the general population. In a sample of 1,435 arrestees drug-tested and interviewed by Bennett and colleagues (2001), 24% tested positive for opioids. The average weekly expenditure on drugs (heroin and crack/cocaine) was £290, and the main sources of illegal income were theft, burglary, robbery, handling stolen goods and fraud. The NTORS also found 61% of a drug misuse treatment sample reported committing crimes other than drug possession in the 3 months prior to starting treatment, with the most commonly reported offence being shoplifting.) In addition, there is a high prevalence of drug misuse among the incarcerated population: in a 1997 survey, between 41 and 54% of remand and sentenced prisoners were reported to be opioid, stimulant and/or cannabis dependent in the year prior to incarceration (Singleton et al., 1999).

The association between drug misuse and crime also applies in the younger population. For example, the Home Office 2004 Offending Crime and Justice Survey (The Information Centre, Lifestyle Statistics, 2006) found that young people who had used drugs in the past year were over twice as likely to have committed an offence compared with those who reported not having used drugs (52% versus 19%). In addition, young offenders who had taken a Class A drug in the past year were more likely to be frequent offenders than those who reported using other types of drugs. However, in contrast to figures for the general population, Class A drug users comprise a very small proportion (1% testing positive for heroin and 4% for cocaine) of arrestees aged

below 18 years (Matrix Research and Consultancy & Institute for Criminal Policy Research, 2007).

Drug treatment can lead to significant reductions in offending levels (Gossop *et al.*, 2003) and, as a consequence, the prison and the broader criminal justice system is an increasingly significant referral source and venue for providing drug treatment.

3.2 EPIDEMIOLOGY OF DRUG MISUSE

According to the national British Crime Survey 2005/6 (Roe & Man, 2006), 34.9% of 16-59 year olds had used one or more illicit drugs in their lifetime, 10.5% in the previous year and 6.3% in the previous month. These figures are much lower for opioid use, with 0.1% of the population having used opioids (including heroin and methadone) in the previous year. However, estimates based on data that also take into account other indicators such as current service usage provide an illicit drug-use figure of 9.35 per thousand of the population aged 15-64 years (360,811), of whom 3.2 per thousand (123,498) are injecting drug users (Chivite-Matthews et al., 2005). Analysis of the 2004/5 data from the NDTMS suggests that there were an estimated 160,450 people in contact with treatment services in England during that period, the majority for primary opioid misuse (NTA, 2005). Males comprise over 70% of new presentations, and the majority of those requiring treatment are opioid dependent (typically using illicit heroin). Similar figures have emerged from Frischer and colleagues (2001), who estimated 0.5% of the population of Britain (that is, 226,000 people) to be problem drug users. More recent estimates indicate that there are around 327,000 problem drug users (of opioids and/or crack cocaine) in the UK, with 280,000 of these opioid users (Hay et al., 2006).

The epidemiology of drug misuse among young people differs considerably from that of the general population. The 2003/4 NDTMS data found cannabis to be the primary problem drug for the majority of young people aged 11–17 years in contact with treatment services (around 60% overall, with a higher figure for males), whereas individuals with primary heroin use comprised a minority of this population.

Drug misuse is more common in certain vulnerable groups. For example, Ward and colleagues (2003) found that among care leavers aged between 14 and 24 years, drug misuse is much higher than in the general population, with three quarters of the sample having at some time misused a drug and over half having misused a drug in the previous month. Levels in the young homeless population are also much higher than the general population, with one survey finding that almost all (95%) of the sample had at some time misused drugs, many (76%) having used cocaine, heroin and/or amphetamine in the previous month.

3.3 AETIOLOGY AND MAINTENANCE OF DRUG MISUSE

Drug misuse is increasingly portrayed in the field as a medical disorder (known as the 'disease model' of drug misuse), in part due to advances in our understanding of the

neurobiology underlying dependence (Volkow & Li, 2005). There is also no question that numerous socioeconomic and psychological factors all play an important part in the aetiology of drug misuse. These conceptualisations are not mutually exclusive; rather they are facets of the multifactorial aetiology of drug misuse.

The most robust evidence highlights peer drug use, availability of drugs and also elements of family interaction, including parental discipline and family cohesion, as significant risk factors for drug misuse (Frischer *et al.*, 2005). In particular, traumatic family experiences such as childhood neglect, homelessness or abuse increase the likelihood that the individual will develop problems with drugs later on in life (Kumpfer & Bluth, 2004). Recent studies of twins, families and people who have been adopted suggest that vulnerability to drug misuse may also have a genetic component (Prescott *et al.*, 2006), although it is unclear whether repeated use is primarily determined by genetic predisposition, or socioeconomic and psychological factors lead an individual to try and then later to use drugs compulsively. Risk factors for heavy, dependent drug use are much more significant when they occur together rather than individually.

A defining characteristic of drug dependence is that drug use begins as a voluntary action to seek a rewarding stimulus, but continued use results in loss of control over the use, despite its negative consequences (Dackis & O'Brien, 2005). The effects of many illicit drugs are mediated via various brain circuits, in particular the mesolimbic systems, which have evolved to respond to basic rewards (such as food and sex) to ensure survival. A diverse range of substances, including opioids, stimulants and cannabis, as well as alcohol and nicotine, all appear to produce euphoric effects via increasing levels of dopamine (a neurotransmitter) in the nucleus accumbens (Dackis & O'Brien, 2005). This has been well demonstrated in human brainimaging studies (Volkow et al., 1999). Euphoria resulting from use then potentiates further use, particularly for those with a genetic vulnerability (see below). Chronic drug use may produce long-lasting changes in the reward circuits, including reductions in dopamine receptor levels (Volkow et al., 1999), and these contribute to the clinical course of drug dependence, including craving, tolerance and withdrawal (Lingford-Hughes & Nutt, 2003). In addition, other types of neurotransmitter systems (for example, opioids, glutamates and cannabinoids) are implicated in the misuse of specific drugs.

Although initiation into drug use does not lead inevitably to regular and problematic use for many people (Anthony *et al.*, 1994), it is clear that when use begins, it often escalates to misuse and sometimes to dependence (tolerance, withdrawal symptoms and compulsive drug taking). Once dependence is established, particularly with opioids, there may be repeated cycles of cessation and relapse extending over decades (National Consensus Development Panel on Effective Medical Treatment of Opiate Addiction, 1998). Vulnerability to use is highest among young people, with most problem drug users initiating by the age of 20 (typically earlier for cannabis). Individuals dependent on drugs often become so in their early twenties and may remain intermittently dependent for many years.

With cannabis and cocaine, recreational use is more common and it is likely that there are different patterns of use, with those taking cocaine being divided between those who take the drug on an episodic basis and those who take it daily; in contrast, usually only a small number of people taking cannabis move to repeated (daily) increasingly heavy use, with many taking the drug intermittently. A general US population survey of 8,098 individuals (Anthony *et al.*, 1994) found that among those who had used cocaine or cannabis in their lifetime, 16.7% and 9.1% subsequently became dependent on the respective drugs; for heroin, the figure was 23.9%. Such differences may relate to the different intensities of action different drugs produce within the neural reward sites (Stimmel & Kreek, 2000).

The neurobiological account of fundamental reward systems implicated in drug misuse may parallel the sociocultural-behavioural-cognitive model presented by Orford (2001). He conceptualised drug misuse as an 'excessive appetite', belonging to the same class of disorders as gambling, eating disorders and sex addiction. All involve activities that form strong attachment, and were once rewarding, but with excessive consumption result in compulsion and negative consequences. Or ord argued that the emotional regulation of such appetitive behaviours in their respective social contexts (for example, the excitement associated with gambling or the anticipation of the next 'fix' of heroin), well characterised within the principles of operant conditioning, is a primary factor driving excessive use. Secondary factors such as internal conflict (knowing that the behaviour is harmful yet being unable to disengage from it) potentiate these emotions and thus excessive use, but an alternative result is that the individual alters behaviour in order to resolve such conflict. This crucially suggests that recovery is not impossible, but also that successful treatment attempts are likely to operate against a background of powerful natural processes (Orford, 2001).

3.4 THE COURSE OF DRUG MISUSE

Drug misuse is a relapsing and remitting condition often involving numerous treatment episodes over several years (Marsden *et al.*, 2004). While the initiation of drug use does not lead inevitably to dependence over the long term (Anthony & Petronis, 1995), a number of factors can potentiate this developmental course. Earlier initiation of drug use increases the likelihood of daily use, which in turn results in a greater likelihood of dependence (Kandel *et al.*, 1986).

Among people who misuse opioids, who form the predominant in-treatment population in the UK, most individuals develop dependence in their late teens or early twenties, several years after first using heroin, and continue using over the next 10–30 years. In a long-term outcome study (up to 33 years) of 581 male opioid users in the US, 30% had positive (or refused) urine tests for opioids, 14% were in prison and 49% were dead (Hser *et al.*, 2001). Longitudinal data from the US also showed that the average time from first to last opioid use was 9.9 years, with 40% dependent for over 12 years (Joe *et al.*, 1990). Although it is the case that problem drug users can cease drug use without any formal treatment (Biernacki, 1986), particularly for individuals with primary cocaine or cannabis misuse, for many it is treatment that alters the course of opioid dependence.

Most initiation of cocaine use occurs around the age of 20, with the risk of cocaine dependence occurring early and explosively after first use, and persisting for an average of 10 years (Anthony *et al.*, 1994).

Cannabis use typically begins in early adolescence with heaviest use in the 15–24 age group (Harkin *et al.*, 1997), which may in part be explained by strong peer influences (Frischer *et al.*, 2005). Most use tends to decline steadily from the mid 20s to the early 30s (Bachman *et al.*, 1997). Cannabis dependence persisting through adulthood is the most prevalent among those with sustained frequent use, as high as 40% among those who have used almost daily (Kandel & Davies, 1992).

Although drug misuse can affect all socioeconomic groups, deprivation and social exclusion are likely to make a significant contribution to the maintenance of drug misuse (ACMD, 1998). That said, an association has been found between income in adolescence and early adulthood and cannabis use (Makkai & McAllister, 1997), which may reflect the recreational nature of the majority of cannabis use.

Factors that influence the cessation of drug use in adulthood are similar to those associated with lack of drug use in adolescence. For example, transitions into social roles with greater conventionality, responsibility and/or contexts that are not favourable to using drugs (such as employment, mortgage, marriage and pregnancy; for example, Bachman *et al.*, 1997) and good health are not associated with long-term use. Peer pressure is a major influence on experimental use and is also likely to affect a move towards regular use. The level of drug use is again a clear predictor of continued use.

Once an individual is dependent, drug use is generally a chronic condition, interspersed with periods of relapse and remission (Marsden *et al.*, 2004). Repeated interaction with the criminal justice system, long-term unemployment and increasing social isolation serve to further entrench drug use.

3.5 THE PHARMACOLOGICAL EFFECTS OF DRUG MISUSE

Opioids

Opioids have many effects on the brain, mediated through specific receptors (μ , κ , or δ). The key opioid receptor subtype is μ , which mediates 'euphoria', as well as respiratory depression, and is the main target for opioids (Lingford-Hughes & Nutt, 2003), while the κ receptor is involved in mood regulation. Drugs such as heroin and methadone are agonists, which stimulate the receptor. Buprenorphine is a partial agonist; that is, it occupies the receptor in the same way but only partially activates it. In addition, it is an antagonist at the κ receptor and therefore is less likely to lower mood compared with μ agonists.

Soon after injection (or inhalation), heroin metabolises into morphine and binds to opioid receptors. This is subjectively experienced as a euphoric rush, normally accompanied by a warm flush, dry mouth, and sometimes nausea, vomiting and severe itching. As the rush wears off, drowsiness, and slowing of cardiac function and breathing (sometimes to the point of death in an overdose), persist for several hours (National Institute on Drug Abuse [NIDA], 2005a). The effects of methadone are

similar but more drawn out and therefore less intense (lasting up to 24 hours when taken orally as prescribed); however, this may be circumvented by illicit users who inject the drug.

The most obvious consequence of long-term opioid use is the development of opioid dependence itself, and the associated harms. Repeated injection will also have medical consequences, such as scarring, infection of blood vessels, abscesses, and compromised functioning of the kidney, liver and lungs (with increased vulnerability to infections).

Stimulants

As central nervous system stimulants, cocaine and amphetamine affect a number of neurotransmitter systems in the brain but exert their effects primarily via dopamine, which mediates reward. Cocaine blocks the presynaptic reuptake of dopamine, such that it is not removed from the intracellular space and leads to extended firing of post-synaptic neurons, resulting in physiological arousal. Amphetamines also increase the availability of dopamine but are thought to do so by triggering a presynaptic leakage.

The acute subjective effects of cocaine are euphoria, increased energy, heightened alertness, sexual arousal, increased sociability and talkativeness. Physiologically there can be acute adverse effects on breathing, and the cardiovascular and central nervous systems: increased heart rate, blood pressure and body temperature, and pupil dilation. All these effects have near-immediate onset but also diminish quickly (after roughly 15–30 minutes if the drug is snorted and 5–10 minutes if smoked), as cocaine is metabolised rapidly by the body (NIDA, 2004). As acute effects wear off, users experience a rebound period ('crash'), which may include restlessness, anxiety, agitation and insomnia. This can lead to the user bingeing on cocaine in an attempt to displace these negative effects. Chronic misuse of cocaine may lead to increased paranoia, inability to concentrate, sexual dysfunction and cognitive deficits.

For amphetamines, the acute effects are broadly similar except that they are long lasting (normally 4–8 hours), due to slower metabolism. Overdoses may lead to dangerously elevated body temperature, convulsions or even death. Chronic misuse may cause long-term damage to the brain's ability to manufacture dopamine, possibly resulting in amphetamine psychosis.

Cannabis

Cannabis affects almost every body system, via cannabinoid receptors in the brain, which regulate a range of cognitive and motor functions (NIDA, 2005b). Within minutes of smoking cannabis, the heart rate increases and the bronchial passages relax. Often the individual experiences intoxication, mild euphoria and increased sociability. However, anxiety or paranoia may sometimes occur, particularly among first-time or psychologically vulnerable users (Johns, 2001). Distorted perceptions are common, for example colours may appear more intense and time may seem to slow down. The euphoria reaches a plateau lasting 2 hours or more, depending on the dose, after which the individual may feel sleepy or depressed.

Cannabis use also impairs memory, attention and motor coordination, with especially dangerous consequences on driving performance. Such effects may last for

many hours after administration of the drug; the numerous metabolites of a single moderate dose of cannabis may require up to 4 weeks to be completely eliminated from the body (Maykut, 1985). The smoke from cannabis contains the same constituents as tobacco smoke; hence chronic cannabis smoking is associated with a range of respiratory tract disorders, including bronchitis, emphysema and cancers (Hashibe *et al.*, 2005; Tashkin, 1990).

3.6 THE PUBLIC HEALTH IMPACT OF DRUG MISUSE

The harms associated with illicit heroin use include increased mortality from overdose and from other directly or indirectly associated harms such as increased risk of infection with blood-borne viruses (HIV, hepatitis B and hepatitis C); high levels of depression and anxiety disorders; social problems such as disrupted parenting, employment and accommodation; and increased participation in income-generating crime.

Mortality, particularly in heroin-dependent users, is high, with estimates of between 12 (Oppenheimer *et al.*, 1994) and 22 times (Frischer *et al.*, 1997) that of the general population. In England and Wales, there were 1,382 drug-related deaths in 2005 (National Programme on Substance Abuse Deaths, 2005). The majority (59%) were cases of accidental poisoning, although a sizeable proportion (16%) was a result of intentional self-poisoning. Opioids (alone or in combination with other drugs) accounted for some 70% of the deaths, and cocaine 13%. Many of the deaths appear to be due to multiple drug toxicity, especially the presence of central nervous system depressants (for example, alcohol and benzodiazepines), rather than simply an 'overdose' of an opioid. This is supported by research that shows those whose deaths were attributed to overdose have opioid levels no higher than those who survive, or than heroin users who die from other causes (Darke & Zador, 1996). Recent cohort studies have shown that mortality rates from methadone-related death are decreasing (Brugal *et al.*, 2005).

HIV infection is a major problem for injecting drug users, with the number of new diagnoses of HIV in the UK holding at around a hundred for the last few years, with 5.6% of all UK diagnoses attributed to injecting drug use by the end of 2005 (Health Protection Agency *et al.*, 2006). There are differences in geographical distribution of HIV in the UK, with rates higher in some centres such as London. Approximately 50% of injecting drug users have been infected with hepatitis C, but this rate, like the HIV prevalence rate, is lower than in many other countries (Health Protection Agency *et al.*, 2006). Transmission of both hepatitis A and B continues even though there are effective vaccines. Needle and syringe sharing increased in the late 1990s, and since then has been stable with around one in three injecting drug users reporting this activity in the last month (Health Protection Agency *et al.*, 2005).

Psychiatric comorbidity is common in drug misuse populations, with anxiety and depression generally common, and antisocial and other personality disorders in opioid-using populations (Regier *et al.*, 1990, 1998). The national US Epidemiological Catchment Area study of the prevalence of mental health disorders

reported a 47% lifetime prevalence rate of substance misuse (drugs and alcohol) among people with schizophrenia compared with 16% in the general population, and found that more than 60% of people with a diagnosis of bipolar I disorder had a lifetime diagnosis of substance misuse disorder. Around one in five of the people in the NTORS sample had previously received treatment for a psychiatric health problem other than substance misuse (Marsden *et al.*, 2000). Drug misuse disorders complicated by other comorbid mental disorders have been recognised as having a poorer prognosis and being more difficult to treat than those without comorbid disorders; comorbid disorders are more likely to be chronic and disabling, and result in greater service utilisation.

Lost productivity and unemployment increase with the severity and duration of drug misuse, and personal relationships are placed under considerable strain by dependent drug use. Problems with accommodation are also common in such groups. For example, prior to intake in the NTORS, 7% of the study group were homeless and living on the street, 5% were living in squats and 8% were living in temporary hostel accommodation (Gossop *et al.*, 1998).

Drug misuse may also have a negative impact on children and families (see Section 3.11). In the UK it is estimated that 2–3% of all children under the age of 16 years have parents with drug problems (ACMD, 2003). While use of opioids does not necessarily impact on parenting capacity, registration on UK child protection registers for neglect has been correlated strongly with parental heroin use, and parental problem drug use has been shown to be one of the commonest reasons for children being received into the care system (Barnard & McKeganey, 2004).

3.7 IDENTIFICATION AND ASSESSMENT OF DRUG MISUSE

So prevalent is drug use that all healthcare professionals, wherever they practice, should be able to identify and carry out a basic assessment of people who use drugs. Many people who misuse drugs do not present to drug treatment services, with perhaps 50% of people who misuse drugs not seeking treatment; however this represents a significant improvement on the position in the UK in the early 1990s, when perhaps only 20% of people who misused drugs sought treatment. Of those who do not seek treatment for their drug misuse, a proportion may nevertheless present to other medical services, the criminal justice system and social care agencies. Many will not be seeking help for their drug problems and many, for example some of those primarily misusing cocaine or cannabis, may not be aware of the potentially harmful effects of their drug use. It is probable that those who present to services for drug treatment have the greatest number of problems (Best *et al.*, 2006b).

Routine screening for drug misuse is largely restricted in the UK to criminal justice settings, including police custody and prisons (Matrix Research and Consultancy & National Association for the Care and Rehabilitation of Offenders [NACRO], 2004); it is sparsely applied in health and social care settings. For example, a recent study of psychiatric inpatients in London found that only 1 in 50 people admitted to hospital had undergone screening for drug misuse (Barnaby *et al.*, 2003).

The NTA's updated Models of Care service framework emphasises the importance of non-specialist (tier 1) services in the identification of drug misuse as a precursor to referral for treatment (NTA, 2006a). Opportunistic methods for the effective identification of drug misuse should therefore be considered in a variety of healthcare settings. These are described in Chapter 6.

For those identified and considering treatment, a good assessment is essential to continuing care. Assessment skills are important across all of those health and social care professionals who may come into contact with drug misuse. Assessment includes information about past and current drug use (amount, type, duration, periods of abstinence and effect of abstinence), history of injecting, risk of HIV and other bloodborne viruses, medical history, forensics and previous contact with treatment services. Assessment is a continuous process carried out at every contact with the individual and his or her healthcare professional, counsellor or social worker and can take place over many years. Urine testing for the absence or presence of drugs is an important part of assessment and monitoring. Formal rating scales may be helpful in assessing outcomes and in certain areas of monitoring, for example of withdrawal symptoms.

The aims of assessment are: to confirm drug use (history, examination and urinal-ysis); assess the degree of dependence; identify complications of drug misuse and assess risk behaviour; identify other medical, social and mental health problems; determine the expectations of treatment and the degree of motivation to change; assess the most appropriate level of expertise required; determine the need for substitute medication; and refer to/liaise appropriately with shared care, specialist or specialised generalist care, or other forms of psychosocial care where appropriate. In addition, immediate advice on harm reduction, including, if appropriate, access to sterile needles and syringes, as well as testing for hepatitis and HIV, and immunisation against hepatitis, should take place.

3.8 THE AIMS OF THE TREATMENT AND MANAGEMENT OF DRUG MISUSE

The clinical management of drug misuse may be categorised into three broad approaches: harm reduction, maintenance-oriented treatments and abstinence-oriented treatments. All treatments aim to prevent or reduce the harms resulting from use of drugs. Care planning and keyworking should form a core part of subsequent treatment and care.

Harm reduction aims to prevent or reduce negative health or other consequences associated with drug misuse, whether to the drug-using individual or, more widely, to society. With such approaches, it is not essential for there to be a reduction in the drug use itself (although, of course, this may be one of the methods of reducing harm). For instance, needle and syringe exchange services aim to reduce transmission of blood-borne viruses through the promotion of safer drug injecting behaviour.

Maintenance-oriented treatments in the UK context primarily refer to the pharmacological maintenance of people who are opioid dependent, through the

prescription of opioid substitutes (methadone or buprenorphine). This therapy aims to reduce or end their illicit drug use and the consequential harms.

Abstinence-oriented treatments aim to reduce an individual's level of drug use, with the ultimate goal of abstinence. The NTORS found that approximately one third of those entering treatment services were abstinent 5 years later (Gossop *et al.*, 2003). However, these treatments may be associated with an increased risk of death from overdose in the event of relapse after a period of abstinence, during which time drug tolerance is lost (Verger *et al.*, 2003). Consequently, it is particularly important for abstinence-oriented treatment to include education on post-detoxification vulnerability to relapse (Gossop *et al.*, 1989) and to overdose, and for wider psychosocial rehabilitation support to be provided.

Care planning should consider the following when any treatment or management plan is developed:

- type and pattern of use
- level of dependence
- comorbid mental and physical health problems
- setting
- age and gender
- service user's aspirations and expectations.

The general principles of treatment are that no single treatment is appropriate for all individuals, treatments should be readily available and begin when the service user presents, and there should be the capacity to address multiple needs. It is also accepted that treatments will change over time. It appears that treatment does not need to be voluntary to be successful – comparisons of voluntary and legally coerced drug treatment have been reviewed recently elsewhere (NCCMH, 2008). For most people in long-term treatment, that is those with opioid dependence, substitute medications, such as methadone and buprenorphine, are important elements of care. However, services also need to address coexisting problems, such as mental health and physical health problems, alongside the drug misuse.

Keyworking forms the core part of treatment for most service users with long-term drug misuse problems (NTA, 2006a). Typically, this involves the following:

- conducting an assessment of need (and a risk assessment)
- establishing and sustaining a therapeutic relationship
- clarification of the service user's goals in relation to his/her drug use
- discussion, implementation, evaluation and revision of a treatment plan to address the client's goals and needs
- liaison and collaboration with other care providers
- integration of a range of interventions based on a biopsychosocial model of drug use (for example, prescribing, addressing needs such as housing and improving personal relationships)
- use of one or more techniques derived from one or more therapeutic models to engage and retain the service user in treatment and to support the treatment plan (for example, use of drug diaries and motivational skills) in the absence of delivering a complete course of formal psychological therapy.

3.9 CURRENT CARE AND TREATMENT IN THE NHS

The British response to drug problems dates back to the report of the Rolleston Committee of 1926. The committee accepted dependence as a disease and established a medical approach to drug problems in Britain rather than the predominantly punitive one pursued in other countries such as the US. Rolleston gave doctors a large degree of clinical freedom in their response to people who were dependent, including the use of maintenance treatment. To this day, maintenance is considered an essential aspect of drug treatment.

A large increase in the number of people with heroin dependence in Britain in the mid-1960s prompted the establishment of a network of drug dependence clinics set in psychiatric hospitals and run directly by the NHS. The second epidemic of heroin use in the early 1980s led to a further reshaping of the British treatment response. A multidisciplinary approach was encouraged through the establishment of community drug teams and attempts to increase general practitioner (GP) involvement in drug treatment, with the first in a series of clinical guidelines setting out the responsibilities of the prescribing doctor (DH, 1999). The guidelines also sought to encourage shared care of the person who misuses drugs by different professional groups. While the drug dependence clinics remained the cornerstone of this reshaped approach, the vast majority of treatment prescriptions, namely oral methadone, were now dispensed by community pharmacists and consumed at home. This was further supported by the 2004 General Medical Services contract provision for enhanced maintenance prescribing services (British Medical Association, 2004).

The emergence of HIV/autoimmune deficiency syndrome (AIDS) in the 1980s led to the introduction of needle and syringe exchange schemes as an addition to the treatment services available. These schemes provided needles and syringes to the dependent and non-dependent injector. Harm reduction also became an important aspect of treatment responses to drug misuse. Another refocusing of drug treatment came in the 1990s, with increased concern over the link between criminal activity and drug misuse. Criminal justice settings were seen as an important conduit for getting people who misuse drugs into treatment and a number of interventions such as Drug Treatment and Testing Orders (DTTOs) were established. In 2003, the Home Office, with the DH and the NTA as its key partners, introduced the Drug Interventions Programme (DIP), which seeks to bring treatment and criminal justice services together in responding to drug misuse (Witton *et al.*, 2004).

Current practice

Much of the current treatment of drug misuse in services directly provided or purchased by the NHS focuses on the treatment of opioid misuse. In large part, this is reactive to the drug problems with which service users present, who may themselves be informed by awareness of relevant treatments as well as their own perceptions of whether their drug use is problematic. Few services are focused solely on the treatment of cocaine and cannabis misuse; often these problems are only addressed when the primary presenting problem is opioid misuse. In particular, the provision of

treatment is almost non-existent for adults who primarily misuse cannabis, although young people are more likely to receive such treatment. The main treatments for opioid misuse are opioid substitution therapies (methadone and buprenorphine), with stabilisation of the drug user being the treatment aim, leading to improved physical health, well-being, social stabilisation and reduced criminality and costs to society. There is also provision of harm-reduction interventions, for example needle and syringe exchange facilities, alongside formal drug treatment, aiming to minimise the health risks resulting from illicit drug use to the individuals themselves as well as to wider society.

Only a minority entering treatment initially chooses abstinence and enforced abstinence appears ineffective. However, approximately one third entering treatment services generally are abstinent 5 years later (at least for a period of time) (Gossop *et al.*, 1998).

Despite the increase in treatment research, current UK practice is not underpinned by a strong evidence base and there is wide variation in the implementation of psychosocial treatment across services. Two factors may contribute to this situation. First, practice tends to be influenced more by the background and training of those delivering treatment within services than by what research has shown to be effective. Second, there is a lack of studies from the UK, with most evidence coming from the US. These studies are reviewed in Chapter 8.

The most common types of psychosocial interventions available in NHS programmes specifically targeting drug-use behaviours might be based on one of a number of models, including cognitive-behavioural (for example, motivational interviewing and relapse prevention), humanistic and 12-step approaches (Wanigaratne *et al.* 2005). Often this is unfocused, and therapist and client may not have a clear understanding of the therapeutic goals or therapeutic method. In addition, there exist formal psychological therapies delivered within adult mental health settings, aiming to address drug users' coexisting mental health problems (NTA, 2006a).

In addition to formal, structured treatment, there is a long tradition in North America and Europe of community-based, peer-led self-help groups for people with substance misuse problems. The most well-established of these deliver the principles of 12-steps, which has its origins in Alcoholics Anonymous (AA). Two such organisations especially relevant to people who misuse drugs are Narcotics Anonymous (NA) and Cocaine Anonymous (CA). The 12-step fellowships of AA and NA largely predate the existing drug treatment field as a medical specialism. AA was founded in the US in 1935 and in the UK in 1947. NA was founded in the US in 1953, and the first UK meeting was held in 1980 (White, 1998).

Brief interventions, typically empathic in nature and lasting up to two sessions, have a variety of potential advantages in the treatment of drug misuse, including ease of delivery and retention of drug users. These interventions can be conducted in a variety of settings, opportunistically to people not in formal drug treatment and as an adjunct to formal, structured drug treatment (Ashton, 2005). Although brief interventions are considered to be an important component of psychosocial treatment in openaccess drug services (for example, NTA, 2002, 2006a), provision of such interventions varies widely throughout England and Wales.

As previously mentioned, the mainstay of current UK drug treatment lies in the pharmacological maintenance of dependent opioid users. Very little is currently known or practiced in relation to managing the misuse of cocaine, amphetamines or cannabis. Recent research on brief interventions provides for potential development in this area, and is covered more extensively in Chapter 7.

Needle and syringe exchange programmes, which provide injecting drug users with clean injecting paraphernalia, have proven effective at helping to reduce the risk of HIV/AIDS (Wodak & Cooney, 2006). Some of these initiatives include opportunities for psychosocial support alongside needle exchanges. Needle and syringe exchange programmes have been established in all drug action team regions in England, with the overwhelming majority providing specialist services alongside pharmacy provision (Abdulrahim *et al.*, 2006), although the level of provision appears to be variable across regions and on average appears to be insufficient to provide injecting drug users with a clean needle/syringe for every instance of injection. Specialist services provide a wider range of harm-reduction interventions (for example, on-site blood-borne virus testing) than pharmacies, but it does not appear that service users in all specialist services receive comprehensive harm-reduction support.

Residential rehabilitation programmes and therapeutic communities for the treatment of drug problems are well established in the UK. These programmes often have abstinence as their goal. They respond to the complex problems related to the drug misuse of their residents by offering respite and highly structured and intensive programmes of support and care as they seek to make fundamental changes to the lifestyles of the residents, and treatment in some programmes is lengthy, lasting 6–12 months (NTA, 2006b).

Most drug treatment is initiated as a result of drug users themselves seeking treatment. However, there has recently been a rapid expansion in forms of legally coerced treatment, whereby the person who misuses drugs is coerced into treatment as an alternative or adjunct to criminal sanctions (Wild et al., 2002). Such treatment may be legally ordered by the court or through referral away from the judicial process, usually following arrest and charge for drug-related and other offences. Despite recent policy shifts of referral away from the courts, however, many people who misuse drugs still serve prison sentences. A recent estimate suggests that around 39,000 prisoners with a serious drug problem are in custody at any one time (All-Parliamentary Group on Prison Health, 2006). Within the prison setting, drug misuse treatment is increasingly being offered following a number of recent developments, including the phased transfer of responsibilities for commissioning healthcare in publicly funded prisons from the Home Office to the NHS (DH, 2006a). While the mainstay of treatment in prison has traditionally been one of detoxification upon admission, there has been a recent policy shift allowing increased access to opioid maintenance therapy and psychosocial interventions.

3.10 SERVICE USER ORGANISATIONS

As outlined in Chapter 5, organisations for people who misuse drugs, such as the 12-step fellowship of NA, were formed in the US before the drug treatment field had

fully defined itself as a medical specialism. Many rehabilitation centres in the US based themselves on the 'concept houses' that developed out of AA. Since this time, a wider range of service-user organisations has developed, encompassing harm reduction and maintenance-oriented goals as well as abstinence.

In the 1980s and 1990s, as harm reduction moved up the agenda due to the advent of HIV and AIDS, organisations such as Drug Dependents Anonymous (DDA) and Mainliners were established. Although the profile of such organisations is now in decline, there has been growth in collaborations amongst clinicians, researchers and service users, most notably in the UK Harm Reduction Alliance. In the late 1990s, there was a move towards forming national drug organisations: the National Drug Users Development Agency (NDUDA) and the Methadone Alliance (later called the Alliance).

Twelve-step treatments have traditionally taken account of service-user experience and indeed such experience forms the bedrock of these programmes. Recently, harm reduction and maintenance-oriented services have started to formally involve service users and take account of their experience. In addition, the NTA was established as a special health authority to increase the availability of drug treatment in the UK and improve its quality. From the outset, the NTA embraced user involvement as a central component of its strategy.

Service-user involvement in service provision has expanded considerably (see Chapter 5). User groups are now widespread in the UK and are firmly established in the drug treatment field. It should be noted, however, that most organisations are unlikely to reflect the views of people under the age of 18, of whom many will have very different needs and experiences from adults.

3.11 DRUG MISUSE AND THE FAMILY

In the literature, drug misuse is seen as both a 'problem *of* the family' and a 'problem *for* the family' (Bancroft *et al.*, 2002). The evidence that points to traumatic family experiences, such as childhood neglect, homelessness, abuse, loss and bereavement, increasing the likelihood that a person will go on to have drug problems (Kumpfer & Bluth, 2004) can be seen as a problem *of* the family.

As 60–80% of people who misuse drugs live or are in regular contact with their family (Stanton & Heath, 2005), and approximately 2–3% of all children under the age of 16 years have parents with a drug problem (ACMD, 2003), drug misuse can also be said to be a problem *for* the family. The impact may be psychological (for example, depression and anxiety), physical (raised blood pressure and ulcers) (Velleman *et al.*, 1993), social (feelings of isolation and work, family and social difficulties [Hudson *et al.*, 2002]) and financial (see Chapter 5).

As a consequence, it is important to address the needs of carers and other family members. In Chapter 5 there is a summary of carers' needs, which may also include coping with stigmatisation and feeling excluded from the treatment plans of their friend or relative, and access to services. Chapter 8 contains a review of psychological interventions for carers.

Appropriate involvement of family members and carers in the assessment and treatment process may also support the family member/carer and facilitate a more successful outcome for the user. There is evidence that families (including parents, children and siblings) have a role to play in effective treatments; see Chapter 8 for the evidence for behavioural couples therapy in cocaine and opioid dependence and family- or couples-based interventions for people who continue to use illicit drugs while having methadone and naltrexone maintenance treatment.

3.12 ECONOMIC IMPACT OF DRUG MISUSE

Drug misuse is a growing public health concern that carries a substantial economic burden. It is associated with high healthcare and social costs, mainly as a result of transmission of infectious disease, crime and violence (Petry *et al.*, 2004). It has been estimated that problematic drug use accounts for annual social costs in England and Wales of approximately £11,961 million, or £35,455 per user, per year (Godfrey *et al.*, 2002). Chronic health problems comprise a significant element of the health and social care costs of drug misuse. It has been estimated that the prevalence of HIV among new injecting drug users in London reaches 4.2% (Judd *et al.*, 2005). Godfrey and colleagues (2002) estimated the median number of HIV-positive injectors in England and Wales in 2002 to comprise 931 asymptomatic individuals, 1,756 symptomatic and 1,007 with AIDS. The same authors estimated the median per person annual cost of combination therapy at £13,381 for asymptomatic, £14,222 for symptomatic and £24,314 for people with AIDS. These estimates yielded median annual costs to the NHS for the treatment for HIV infected drug users of £12.5 million, £25 million and £24 million, respectively, totalling over £60 million.

In 1999, the reported prevalence of hepatitis B in injecting drug users was estimated at 25% among those attending agencies in London and 17% outside London, with a combined estimate for England and Wales of 21% (Godfrey *et al.*, 2002). Based on these estimates, the same study calculated that the number of injecting drug users who were infected with hepatitis B in 2002 was roughly 54,000. An annual cost of £143 per year assumes a lifetime cost of £4,300 to treat people with hepatitis over their average life expectancy of 30 additional years (Godfrey *et al.*, 2002). The annual NHS treatment cost of hepatitis B for injecting drug users was therefore calculated at approximately £7.8 million (Godfrey *et al.*, 2002). Similar estimates for hepatitis C (based on a median 2002 estimate of 81,782 injecting drug users with the virus) yielded an annual NHS treatment cost of £11.7 million (Godfrey *et al.*, 2002). Beyond the healthcare costs incurred directly by the users, the NHS costs relating to treatment of neonates affected by their mothers' drug misuse were calculated at £4.3 million per year (Godfrey *et al.*, 2002), with the annual cost of social services in caring for these children amounting to £63 million.

Including primary care, emergency departments, inpatient care, community mental health, and inpatient mental healthcare, problem drug users are estimated to cost the health service between £283 million and £509 million per year (Godfrey *et al.*, 2002). This estimate was in addition to psychosocial interventions, which at

present cost £1,000 per user, per year (Godfrey *et al.*, 2002). Furthermore, drug misuse increases substantially crime-ralated costs. Godfrey and colleagues (2002) estimated that the criminal justice system and crime victim costs were £2,366 million and £10,556 million respectively, based on the medium estimates of the number of problematic drug users. Criminal justice costs include costs associated with drug arrests for acquisitive crimes, stays in police custody, appearances in court, and stays in prison; crime victim costs refer to material or physical damage, crime victims' loss and expenditures taken in anticipation of crime.

The above estimates did not consider the impact of current drug use on future healthcare demands, the lost output of the victim or perpetrator of crime, nor the intangible effects on the community at large, such as security expenditure, property depreciation or increased reliance on private transportation. It is therefore evident that drug misuse places a considerable economic burden to the health service and the society as a whole.

3.13 CLINICAL PRACTICE RECOMMENDATIONS

- 3.13.1.1 People who misuse drugs should be given the same care, respect and privacy as any other person.
- 3.13.1.2 To enable people who misuse drugs to make informed decisions about their treatment and care, staff should explain options for abstinence-oriented, maintenance-oriented and harm-reduction interventions at the person's initial contact with services and at subsequent formal reviews.
- 3.13.1.3 When making an assessment and developing and agreeing a care plan, staff should consider the service user's:
 - medical, psychological, social and occupational needs
 - history of drug use
 - experience of previous treatment, if any
 - goals in relation to his or her drug use
 - treatment preferences.
- 3.13.1.4 Staff who are responsible for the delivery and monitoring of the agreed care plan should:
 - establish and sustain a respectful and supportive relationship with the service user
 - help the service user to identify situations or states when he or she is vulnerable to drug misuse and to explore alternative coping strategies
 - ensure that all service users have full access to a wide range of services
 - ensure that maintaining the service user's engagement with services remains a major focus of the care plan
 - maintain effective collaboration with other care providers.

4. METHODS USED TO DEVELOP THIS GUIDELINE

4.1 OVERVIEW

The development of this guideline drew upon methods outlined by NICE (*The Guidelines Manual*¹ [NICE, 2006a]). A team of healthcare professionals, lay representatives and technical experts known as the GDG, with support from the NCCMH staff, undertook the development of a patient-centred, evidence-based guideline. There are six basic steps in the process of developing a guideline:

- Define the scope, which sets the parameters of the guideline and provides a focus and steer for the development work.
- Define clinical questions considered important for practitioners and service users.
- Develop criteria for evidence searching and search for evidence.
- Design validated protocols for systematic review and apply to evidence recovered by search.
- Synthesise and (meta-) analyse data retrieved, guided by the clinical questions, and produce evidence profiles.
- Answer clinical questions with evidence-based recommendations for clinical practice.

The clinical practice recommendations made by the GDG are therefore derived from the most up-to-date and robust evidence base for the clinical and cost effectiveness of psychosocial interventions for people who misuse drugs. In addition, to ensure a service user and carer focus, the concerns of service users and carers regarding health and social care have been highlighted and addressed by recommendations agreed by the whole GDG.

4.2 THE SCOPE

Guideline topics are selected by the Department of Health (DH) and the Welsh Assembly Government, which identify the main areas to be covered by the guideline in a specific remit (see *The Guideline Development Process – An Overview for Stakeholders, the Public and the NHS (second edition)*² [NICE, 2006b]). The remit for this guideline was translated into a scope document by staff at the NCCMH.

The purpose of the scope was to:

- provide an overview of what the guideline would include and exclude
- identify the key aspects of care that must be included

¹ Available from: www.nice.org.uk

² Available from: www.nice.org.uk

- set the boundaries of the development work and provide a clear framework to enable work to stay within the priorities agreed by NICE and the National Collaborating Centre and the remit from the DH/Welsh Assembly Government
- inform the development of the clinical questions and search strategy
- inform professionals and the public about the expected content of the guideline
- keep the guideline to a reasonable size to ensure that its development could be carried out within a 12-month period.

The draft scope was subject to consultation with stakeholders over a 4-week period. During the consultation period, the scope was posted on the NICE website (www.nice.org.uk) and comments were invited from stakeholder organisations and the Guideline Review Panel (GRP). Further information about the GRP can also be found on the NICE website. The NCCMH and NICE reviewed the scope in light of comments received, and the revised scope was signed off by the GRP.

4.3 THE GUIDELINE DEVELOPMENT GROUP

The GDG consisted of: two service users and a carer, and professionals from psychiatry, clinical psychology, general practice, the prison service, the NTA and the private and voluntary sectors. The guideline development process was supported by staff from the NCCMH, who undertook the clinical and health economics literature searches, reviewed and presented the evidence to the GDG, managed the process and contributed to drafting the guideline.

4.3.1 Guideline Development Group meetings

Nine GDG meetings were held between November 2005 and March 2007. During each day-long GDG meeting, in a plenary session, clinical questions and clinical and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GDG members declared any potential conflicts of interest, and service user and carer concerns were routinely discussed as part of a standing agenda.

4.3.2 Topic groups

The GDG divided its workload along clinically relevant lines to simplify the guideline development process, and GDG members formed smaller topic groups to undertake guideline work in that area of clinical practice. Topic Group 1 covered questions relating to identification and recognition; topic group 2 covered brief interventions and the reduction of injection and sexual risk behaviours; topic group 3 covered formal psychological interventions; and topic group 4 covered inpatient and prison settings. These groups were designed to efficiently manage the large volume of evidence appraisal prior to presenting it to the GDG as a whole. Each topic group was chaired by a GDG member with expert knowledge of the topic area (one of the healthcare professionals). Topic groups refined the clinical questions and the clinical definitions of treatment interventions, reviewed and prepared the evidence with the systematic reviewer before presenting it to the GDG as a whole and helped the GDG to identify further expertise in the topic. Topic group leaders reported the status of the group's work as part of the standing agenda. They also introduced and led the GDG discussion of the evidence review for that topic and assisted the GDG Chair in drafting the section of the guideline relevant to the work of each topic group.

4.3.3 Service users and carers

Individuals with direct experience of services gave an integral service-user focus to the GDG and the guideline. The GDG included two service users and a carer. They contributed as full GDG members to writing the clinical questions, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline, and bringing service-user research to the attention of the GDG. In drafting the guideline, they contributed to writing the introduction to the guideline topic (Chapter 3) and the chapter on service user involvement and experience, which included a section on the impact of drug misuse on carers (Chapter 5). Finally they identified recommendations from the service user and carer perspective.

4.3.4 National and international experts

National and international experts in the area under review were identified through the literature search and through the experience of the GDG members. These experts were contacted to recommend unpublished or soon-to-be published studies in order to ensure up-to-date evidence was included in the development of the guideline. They informed the group about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost effectiveness of treatment and trial data if the GDG could be provided with full access to the complete trial report. Appendix 5 lists researchers who were contacted.

4.4 CLINICAL QUESTIONS

Clinical questions were used to guide the identification and interrogation of the evidence base relevant to the topic of the guideline. Before the first GDG meeting, draft questions were prepared by NCCMH staff based on the scope and an overview of existing guidelines. They were then discussed by the GDG at their first two meetings and amended as necessary. Where appropriate, the questions were refined once the evidence had been searched and, where needed, sub-questions were generated. The final list of clinical questions can be found in Appendix 6.

For questions about interventions, the PICO (patient, intervention, comparison and outcome) framework was used. This structured approach divides each question into four components: the patients (the population under study), the interventions (what is being done), the comparisons (other main treatment options) and the outcomes (the measures of how effective the interventions have been) (see Text Box 2).

Text Box 2: Features of a well-formulated question on effectiveness of an intervention – the PICO guide

Patients/population	Which patients or population of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?
Intervention	Which intervention, treatment or approach should be used?
Comparison	What is/are the main alternative/s to compare with the intervention?
Outcome	What is really important for the patient? Which outcomes should be considered: intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning and other measures such as quality of life; general health status; costs?

For questions relating to diagnosis, the PICO framework was not used, since such questions do not involve an intervention designed to treat a particular condition. Rather, the questions were designed to pick up key issues specifically relevant to diagnostic tests, for example their accuracy, reliability, safety and acceptability to the patient.

In some situations, the prognosis of a particular condition is of fundamental importance, over and above its general significance in relation to specific interventions. Areas where this is particularly likely to occur relate to assessment of risk, for example in terms of behaviour modification or screening and early intervention. In addition, questions related to issues of service delivery are occasionally specified in the remit from the DH/Welsh Assembly Government. In these cases, appropriate clinical questions were developed to be clear and concise.

To help facilitate the literature review, a note was made of the best study design type to answer each question. There are four main types of clinical question of relevance to NICE guidelines. These are listed in Text Box 3. For each type of question, the best primary study design varies, where 'best' is interpreted as 'least likely to give misleading answers to the question'.

However, in all cases, a well-conducted systematic review of the appropriate type of study is likely to always yield a better answer than a single study.

Text Box 3: Best study design to answer each type of question

Type of question	Best primary study design
Effectiveness or other impact of an intervention	Randomised controlled trial (RCT); other studies that may be considered in the absence of an RCT are the following: internally/externally controlled before and after trial, interrupted time-series
Accuracy of information (for example, risk factor, test, prediction rule)	Comparing the information against a valid gold standard in a randomised trial or inception cohort study
Rates (of disease, patient experience, rare side effects)	Cohort, registry, cross-sectional study
Costs	Naturalistic prospective cost study

Deciding on the best design type to answer a specific clinical or public health question does not mean that studies of different design types addressing the same question were discarded.

4.5 SYSTEMATIC CLINICAL LITERATURE REVIEW

The aim of the clinical literature review was to systematically identify and synthesise relevant evidence from the literature in order to answer the specific clinical questions developed by the GDG. Thus, clinical practice recommendations are evidence based, where possible, and, if evidence is not available, informal consensus methods are used (see Section 4.5.6) and the need for future research is specified.

4.5.1 Methodology

A step-wise, hierarchical approach was taken to locating and presenting evidence to the GDG. The NCCMH developed this process based on methods set out in *The Guidelines Manual* (NICE, 2006a)³ and after considering recommendations from a range of other sources. These included:

- Clinical Policy and Practice Program of the New South Wales Department of Health
- Clinical Evidence online
- The Cochrane Collaboration

³ Available from: www.nice.org.uk

- Grading of Recommendations: Assessment, Development and Evaluation (GRADE) Working Group
- New Zealand Guidelines Group
- NHS Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Oxford Systematic Review Development Programme
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Agency for Healthcare Research and Quality.

4.5.2 The review process

After the scope was finalised, a more extensive search for systematic reviews and published guidelines was undertaken. Existing NICE guidelines were updated where necessary. Other relevant guidelines were assessed for quality using the AGREE instrument (AGREE Collaboration, 2003). The evidence base underlying high-quality existing guidelines was utilised and updated as appropriate.

At this point, the review team, in conjunction with the GDG, developed a review protocol that detailed all comparisons necessary to answer the clinical questions. The initial approach taken to locating primary-level studies depended on the type of clinical question and availability of evidence.

The GDG decided which questions were best addressed by good practice based on expert opinion, which questions were likely to have a good evidence base and which questions were likely to have little or no directly relevant evidence. Recommendations based on good practice were developed by informal consensus of the GDG. For questions with a good evidence base, the review process depended on the type of key question (see below). For questions that were unlikely to have a good evidence base, a brief descriptive review was initially undertaken by a member of the GDG.

Searches for evidence were updated 6–8 weeks before the stakeholder consultation. After this point, studies were included only if they were judged by the GDG to be exceptional (for example, the evidence was likely to change a recommendation).

The search process for questions concerning interventions

For questions related to interventions, the initial evidence base was formed from well-conducted RCTs that addressed at least one of the clinical questions. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, the RCT remains the most important method for establishing treatment efficacy (this is discussed in more detail in appropriate clinical evidence chapters). For other clinical questions, searches were for the appropriate study design.

All searches were based on the standard mental health related bibliographic databases (EMBASE, MEDLINE, PsycINFO, Cochrane Library and CINAHL) for all trials potentially relevant to the guideline.

Where the evidence base was large, recent high-quality English-language systematic reviews were used primarily as a source of RCTs (see Appendix 9 for quality

criteria used to assess systematic reviews). However, in some circumstances existing datasets were utilised. Where this was the case, data were cross-checked for accuracy before use. New RCTs meeting inclusion criteria set by the GDG were incorporated into the existing reviews and fresh analyses performed.

After the initial search results were scanned liberally to exclude irrelevant papers, the review team used a purpose built 'study information' database to manage both the included and the excluded studies (eligibility criteria were developed after consultation with the GDG). For questions without good quality evidence (after the initial search), a decision was made by the GDG about whether to (a) repeat the search using subject-specific databases (for example, AMED, SIGLE or PILOTS), (b) conduct a new search for lower levels of evidence, or (c) adopt a consensus process (see Section 4.5.6). Future guidelines will be able to update and extend the usable evidence base starting from the evidence collected, synthesised and analysed for this guideline.

In addition, searches were made of the reference lists of all eligible systematic reviews and included studies, as well as the list of evidence submitted by stakeholders. Known experts in the field (see Appendix 5), based both on the references identified in early steps and on advice from GDG members, were sent letters requesting relevant studies that were in the process of being published⁴. In addition, the tables of contents of appropriate journals were periodically checked for relevant studies.

The search process for questions of diagnosis and prognosis

For questions related to diagnosis and prognosis, the search process was the same as described above, except that the initial evidence base was formed from studies with the most appropriate and reliable design to answer the particular question. That is, for questions about diagnosis, the initial search was for cross-sectional studies and for questions about prognosis, it was for cohort studies of representative patients. In situations where it was not possible to identify a substantial body of appropriately designed studies that directly addressed each clinical question, a consensus process was adopted (see Section 4.5.6).

Search filters

Search filters developed by the review team consisted of a combination of subject heading and free-text phrases. Specific filters were developed for the guideline topic and, where necessary, for each clinical question. In addition, the review team used filters developed for systematic reviews, RCTs and other appropriate research designs (see Appendix 7).

Study selection

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database. Eligibility criteria were developed for each clinical question

⁴Unpublished full trial reports were also accepted where sufficient information was available to judge eligibility and quality (see section below on unpublished evidence).

and are described in the relevant clinical evidence chapters. Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (see Appendix 9 and Appendix 14). The eligibility of each study was confirmed by at least one member of the appropriate topic group.

Studies of young people and adults were included. For the purposes of this guideline, a young person was defined as an individual aged 16 to 18, and studies were included for review only if they were judged to include a significant proportion of participants aged 16 or above. In each included study, at least 50% of participants had to be aged 16 years or over; where such information was not provided, mean age had to be greater than or equal to 15.5 years.

For some clinical questions, it was necessary to prioritise the evidence with respect to the UK context (that is, external validity). To make this process explicit, the topic groups took into account the following factors when assessing the evidence:

- participant factors (for example, gender, age and ethnicity)
- provider factors (for example, model fidelity, the conditions under which the intervention was performed and the availability of experienced staff to undertake the procedure)
- cultural factors (for example, differences in standard care and differences in the welfare system).

It was the responsibility of each topic group to decide which prioritisation factors were relevant to each clinical question in light of the UK context and then decide how it should modify its recommendations.

Unpublished evidence

The GDG used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess the quality of the data. Second, the evidence must have been submitted with the understanding that data from the study and a summary of the study's characteristics would be published in the full guideline (therefore, the GDG did not accept evidence submitted as commercial in confidence). However, the GDG recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

4.5.3 Data extraction and synthesising the evidence

Outcome data were extracted from all eligible studies that met the quality criteria. Where possible, meta-analysis was used to synthesise the evidence using Review Manager 4.2.8 (Cochrane Collaboration, 2005). If necessary, reanalyses of the data or sub-analyses were used to answer clinical questions not addressed in the original studies or reviews.

Where possible, dichotomous efficacy outcomes were calculated on an intention-to-treat basis (that is, a 'once-randomised-always-analyse' basis). This assumes that those participants who ceased to engage in the study – from whatever group – had an

unfavourable outcome. Adverse effects were entered into Review Manager as reported by the study authors because it was usually not possible to determine whether early withdrawals had an unfavourable outcome. For the outcome 'leaving the study early for any reason', the denominator was the number randomised.

Included/excluded studies tables, generated automatically from the study information database, were used to summarise general information about each study (see Appendix 14). Where meta-analysis was not appropriate and/or possible, the reported results from each primary-level study were also presented in the included studies table (and included, where appropriate, in a narrative review).

Consultation was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by one reviewer and cross-checked with the existing dataset. Where possible, two independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by one reviewer was checked by the second reviewer. Disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias (Jadad *et al.*, 1996; Berlin, 1997).

4.5.4 Presenting the data to the GDG

Summary characteristics tables and, where appropriate, forest plots generated with Review Manager were presented to the GDG in order to prepare an evidence profile for each review and to develop recommendations.

Evidence profile tables

An evidence profile table was used to summarise both the quality of the evidence and the results of the evidence synthesis (see Table 1 for an example of an evidence profile table). Each table included details about the quality assessment of each outcome: number of studies, the study design, limitations (based on the quality of individual studies; see Appendix 9 for the quality checklists and Appendix 14 for details about each study), information about the consistency of the evidence (see below for how consistency was measured), directness of the evidence (that is, how closely the outcome measures, interventions and participants match those of interest) and any other considerations (for example, effect sizes with wide confidence intervals [CIs] would be described as imprecise data). Each evidence profile also included a summary of the findings: number of patients included in each group, an estimate of the magnitude of the effect, and quality of the evidence. The quality of the evidence was based on the quality assessment components (study design, limitations to study quality, consistency, directness and any other considerations) and graded using the following definitions:

- **High** = Further research is very unlikely to change our confidence in the estimate of the effect.
- **Moderate** = Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate.

Table 1: Example of GRADE evidence profile for methadone maintenance treatment (MMT) plus contingency management (CM) versus methadone maintenance treatment plus control (not all outcomes are shown)

			olity occoesmon	,				Summary	Summary of findings			
		n>	Quality assessinein	1		No of patients	ients	E	Effect			
No of studies		Design Limitations Consistency	Consistency	Directness	Other considerations	MMT + CM	MMT + control	Relative Absolute (95% CI)	Absolute (95% CI)	Quality	Quality Importance	
Minimu Silverm	um 3–26 an, 2004	Minimum 3–26 weeks' abstin Silverman, 2004; Stitzer, 1992)	nence (Chutuap	e, 2001; McC	Minimum 3–26 weeks' abstinence (Chutuape, 2001; McClellan, 1993; Petry, 2002; Pierce, 2006; Rawson, 2002; Schottenfeld, 2005; Silverman, 1998; Silverman, 2004; Stitzer, 1992)	, 2002; Pierce, 2	.006; Raws	on, 2002; Sc	hottenfeld, 2	005; Silver	man, 1998;	
6	RCT	No limitations	No important Some Strong inconsistency uncertainty association $(-1)^1$ $(+1)^2$	Some uncertainty $(-1)^1$	Strong association $(+1)^2$	130/403 (32.3%)	34/404 (8.4%)	RR 3.89 (2.78 to 5.45)	1	Review: Comparison: Outcome:	6	
Minim	um 3–6 v	weeks' abstin	ence (Petry, 200	02; Rawson,	Minimum 3-6 weeks' abstinence (Petry, 2002; Rawson, 2002; Silverman, 1998; Stitzer, 1992)	998; Stitzer, 199	12)					
4	RCT	No limitations ³	No No important Some Strong limitations ³ inconsistency uncertainty association $(-1)^1$ $(+1)^2$	Some uncertainty $(-1)^1$	Strong association (+1) ²	48/94 51.1%	15/97 15.5%	RR 3.28 (2.00 to 5.36)	1	Review: Comparison: Outcome:	6	
Minim	um 8–12	weeks' absti	nence (Chutuap	e, 2001; Mc	Minimum 8-12 weeks' abstinence (Chutuape, 2001; McClellan, 1993; Pierce, 2006; Schottenfeld, 2005)	e, 2006; Schott	enfeld, 200.	5)				
4	RCT	No limitations	No important Some Strong inconsistency uncertainty association $(-1)^1$ $(+1)^2$	Some uncertainty $(-1)^1$	Strong association (+1) ²	71/283 25.1%	19/281	RR 3.87 (2.43 to 6.16)	ı	Review: Comparison: Outcome:	6	
Minim	um of 26	weeks' absti	Minimum of 26 weeks' abstinence (Silverman, 2004)	ian, 2004)								
1	RCT	No limitations ³	Important inconsistency $(-1)^2$	Some uncertainty $(-1)^{1}$	No Important Some Imprecise or limitations ³ inconsistency uncertainty sparse data $(-1)^3$ $(-1)^1$ Very strong association $(+2)^4$	11/26 42.3%	0/26 0%	RR 23.00 (1.43 to 371.00)	I	Review: Comparison: Outcome:	6	
												1

Abstine	ence (6-n	nonth follow-	Abstinence (6-month follow-up) (Rawson; 2002; Petry, 2005c)	2002; Petry, 2	2005c)						
2	RCT	No limitations	No important inconsistency	Some uncertainty $(-1)^1$	None	28/70 40%	15/67 22.4%	RR 1.81 (1.07 to 3.06)	I	⊕⊕⊕O Moderate	6
Abstine	ence fror	n cocaine (6-)	Abstinence from cocaine (6-month follow-up) (Petry, 2002)	ıp) (Petry, 20	002)						
П	RCT	No limitations	No important inconsistency	Some uncertainty $(-1)^1$	Some Imprecise or 19/22 uncertainty sparse data $(-1)^3$ 8.6% $(-1)^1$ Strong association $(+1)^5$	19/221 8.6%	23/639	I	SMD -1.43 (-2.12 to 0.75)	⊕⊕⊕O Moderate	6
Abstine	ence (12-	month follow	Abstinence (12-month follow-up) (Rawson,	2002)						_	
	RCT	No limitations	No important inconsistency	Some uncertainty $(-1)^1$	Some Imprecise or $(-1)^1$ sparse data $(-1)^3$ 53.3% $(-1)^1$	16/30 53.3%	8/30 26.7%	RR 2.00 (1.01 to 3.95)	1	HOOW Low	6

 1 No UK studies 2 RR > 2 3 One small study 4 RR > 5 5 SMD > 100

- Low = Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate.
- Very low = Any estimate of effect is very uncertain.

 For further information about the process and the rationale of producing an evidence profile table, see GRADE (2004).

Forest plots

Forest plots were used to present the results of the meta-analyses to the GDG (see Appendix 15). Each forest plot displayed the effect size and CI for each study, as well as the overall summary statistic.

For dichotomous data, the graphs were generally organised so that the display of data in the area to the right of the 'line of no effect' indicated a favourable outcome for the treatment in question. Dichotomous outcomes were presented as relative risks (RRs) with the associated 95% CI (for an example, see Figure 1). A relative risk (or risk ratio) is the ratio of the treatment event rate to the control event rate. An RR of 1 indicates no difference between treatment and control.

Review: DMP: Brief Interventions Comparison: 01 Brief interventions for people not in formal drug treatment vs Control 01 Abstinence from stimulants (6-month follow-up) Outcome: Brief interventions Weight RR (fixed) 95% CI or sub-category n/N n/N 95% CI 13/74 Baker 2005 25/74 8.44 1.92 [1.07, 3.46] Remetein 2005 90/403 63/375 42 39 1.33 [1.00, 1.78] 78/176 1.17 [0.94, 1.46] Marsden2006 86/166 49 17 Total (95% CI) 1.30 [1.09, 1.55] Total events: 201 (Brief interventions), 154 (Control) Test for heterogeneity: $Chi^2 = 2.62$, df = 2 (P = 0.27), $I^2 = 23.6\%$ Test for overall effect: Z = 2.99 (P = 0.003) 0.1 0.2 0.5 1 2 5 10 Favours control Favours brief

Figure 1: Example of a forest plot displaying dichotomous data

The CI shows with 95% certainty the range within which the true treatment effect should lie and can be used to determine statistical significance. If the CI does not cross the 'line of no effect', the effect is statistically significant.

For continuous data, the graphs were generally organised so that the display of data in the area to the left of the 'line of no effect' indicated a favourable outcome for the treatment in question. Continuous outcomes were analysed as weighted mean differences (WMD), or as standardised mean differences (SMD) when different measures were used in different studies to estimate the same underlying effect (for an example, see Figure 2). If provided, intention-to-treat data, using a method such as 'last observation carried forward', were preferred over data from completers.

To check for consistency between studies, both the I^2 test of heterogeneity and a visual inspection of the forest plots were used. The I^2 statistic describes the proportion of total variation in study estimates that is due to heterogeneity (Higgins & Thompson, 2002). The I^2 statistic was interpreted in the following way:

• >50%: notable heterogeneity (an attempt was made to explain the variation, for example outliers were removed from the analysis or sub-analyses were conducted

to examine the possibility of moderators. If studies with heterogeneous results were found to be comparable, a random-effects model was used to summarise the results (DerSimonian & Laird, 1986). In the random-effects analysis, heterogeneity is accounted for both in the width of CIs and in the estimate of the treatment effect. With decreasing heterogeneity, the random-effects approach moves asymptotically towards a fixed-effects model).

- 30–50%: moderate heterogeneity (both the chi-squared test of heterogeneity and a visual inspection of the forest plot were used to decide between a fixed- and random-effects model).
- <30%: mild heterogeneity (a fixed-effects model was used to synthesise the results).

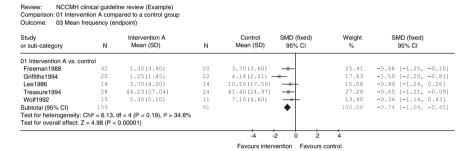


Figure 2: Example of a forest plot displaying continuous data

4.5.5 Forming the clinical summaries and recommendations

The included study tables, forest plots and evidence profiles formed the basis for developing the evidence summaries and recommendations.

For intervention studies, quality assessment was conducted using SIGN methodology (SIGN, 2002) and classified according to a hierarchy (see Text Box 4).

Once the evidence profile tables and evidence summaries were finalised and agreed by the GDG, recommendations were developed, taking into account factors from the evidence, including trade-offs between the benefits and risks of treatment. Other important factors that were considered in developing recommendations included economic considerations, values of the GDG and society, and the group's awareness of practical issues (Eccles *et al.*, 1998).

4.5.6 Consensus method used to answer a key question in the absence of appropriately designed, high-quality research

In the absence of level-1 evidence (or a level that is appropriate to the question), or where the GDG were of the opinion (on the basis of previous searches or their knowledge of the literature) that there was unlikely to be such evidence, a consensus process was adopted. This process focused on those questions that the GDG considered a priority.

Text Box 4: Levels of evidence for intervention studies

Level	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias*
2++	High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case—control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case–control or cohort studies with a high risk of confounding bias or chance and a significant risk that the relationship is not causal*
3	Non-analytic studies (for example, case reports and case series)
4	Expert opinion, consensus methods

^{*}Studies with a level of evidence '-' should not be used as a basis for making a recommendation. Reproduced with permission from SIGN.

The starting point for the process of consensus was that a member of the topic group identified, with help from the systematic reviewer, a narrative review that most directly addressed the key question. Where this was not possible, a brief review of the recent literature was initiated.

This existing narrative review or new review was used as a basis for beginning an iterative process to identify lower levels of evidence relevant to the clinical question and to lead to written statements for the guideline. The process involved a number of steps:

- 1. A description of what is known about the issues concerning the clinical question was written by one of the topic group members.
- 2. Evidence from the existing review or new review was then presented in narrative form to the GDG and further comments were sought about the evidence and its perceived relevance to the clinical question.
- 3. Based on the feedback from the GDG, additional information was sought and added to the information collected. This may include studies that did not directly address the clinical question but were thought to contain relevant data.
- 4. If, during the course of preparing the report, a significant body of primary-level studies (of appropriate design to answer the question) were identified, a full systematic review was conducted.

- 5. At this time, subject possibly to further reviews of the evidence, a series of statements that directly addressed the clinical question was developed.
- 6. Following this, on occasion and as deemed appropriate by the GDG, the report was then sent to appointed experts outside of the GDG for peer review and comment. The information from this process was then fed back to the GDG for further discussion of the statements.
- 7. Recommendations were then developed and could also be sent for further external peer review.
- 8. After this final stage of comment, the statements and recommendations were again reviewed and agreed upon by the GDG.

4.6 SYSTEMATIC ECONOMIC LITERATURE REVIEW

The aim of the economic literature review was to contribute to the guideline's development by providing evidence on the relative cost effectiveness of different treatment options covered in the guideline. This process had two stages:

- identification of the areas with likely major cost impacts within the scope of the guideline
- systematic review of existing evidence on the cost effectiveness of different psychosocial treatment options for problem drug misuse.

In areas with likely major resource implications where economic evidence did not already exist, economic modelling was undertaken alongside the guideline development process, in order to provide cost-effectiveness evidence and assist decision making.

4.6.1 Key economic issues

The following areas relating to the management of drug misuse were identified by the GDG in collaboration with the health economist as the key issues that should be considered in the guideline:

- cost effectiveness of brief interventions for people not in formal drug treatment or those seeking drug treatment and who misuse cannabis or stimulants
- cost effectiveness of contingency management (CM) interventions to improve compliance with physical healthcare for problems associated with drug misuse (hepatitis B and C, human immunodeficiency virus [HIV] and tuberculosis [TB])
- cost effectiveness of contingency management added to standard treatment for cocaine users
- cost effectiveness of cognitive behavioural therapy (CBT) versus waitlist for cannabis users
- cost effectiveness of contingency management for people who are already receiving opioid agonist maintenance treatment and who misuse an additional opioid, stimulant and/or cannabis.

4.6.2 Search strategy

For the systematic review of economic evidence on psychosocial interventions for drug misuse the standard mental health related bibliographic databases (EMBASE, MEDLINE, CINAHL and PsycINFO) were searched. For these databases, a health economics search filter adapted from the Centre for Reviews and Dissemination at the University of York was used in combination with a general filter for drug misuse. The subject filter employed a combination of free-text terms and medical subject headings, with subject headings having been exploded. Additional searches were performed in specific health economics databases (NHS EED, OHE HEED), as well as in the HTA database. For the HTA and NHS EED databases, the general filter for drug misuse was used. OHE HEED was searched using a shorter, database-specific strategy. Initial searches were performed in April 2006. The searches were updated regularly, with the final search between 4 and 6 weeks before the final submission to NICE.

In parallel to searches of electronic databases, reference lists of eligible studies and relevant reviews were searched by hand. Studies included in the clinical evidence review were also screened for economic evidence.

The systematic search for economic evidence on psychosocial interventions for drug misuse resulted in 33 potentially relevant studies. Full texts of all potentially eligible studies (including those for which relevance/eligibility was not clear from the abstract) were obtained. These publications were then assessed against a set of standard inclusion criteria by the health economists, and papers eligible for inclusion were subsequently assessed for internal validity. The quality assessment was based on the checklists used by the *British Medical Journal* to assist referees in appraising full and partial economic analyses (Drummond & Jefferson, 1996) (see Appendix 11).

4.6.3 Selection criteria

The following inclusion criteria were applied to select studies identified by the economic searches for further analysis:

- No restriction was placed on language or publication status of the papers.
- Studies published from 1990 onwards were included. This date restriction
 was imposed in order to obtain data relevant to current healthcare settings
 and costs.
- Only studies from Organisation for Economic Co-operation and Development countries were included, as the aim of the review was to identify economic information transferable to the UK context.
- Selection criteria based on types of clinical conditions and patients were identical to the clinical literature review.
- Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable.

• Full economic evaluations that compared two or more options and considered both costs and consequences (that is, cost-minimisation analysis [CMA], cost-consequences analysis [CCA], cost-effectiveness analysis [CEA], cost-utility analysis [CUA] or cost-benefit analysis [CBA]).

4.6.4 Data extraction

Data were extracted by the health economist using a standard economic data extraction form (see Appendix 12).

4.6.5 Presentation of the results

The economic evidence identified by the health economics systematic review is summarised in the respective chapters of the guideline, following presentation of the clinical evidence. The characteristics and results of all economic studies included in the review are provided in the form of evidence tables in Appendix 13. Results of additional economic modelling undertaken alongside the guideline development process are also presented in the relevant chapters.

4.7 STAKEHOLDER CONTRIBUTIONS

Professionals, service users and companies have contributed to and commented on the guideline at key stages in its development. Stakeholders for this guideline include:

- service user/carer stakeholders: the national service user and carer organisations that represent people whose care is described in this guideline
- professional stakeholders: the national organisations that represent healthcare professionals who are providing services to service users
- commercial stakeholders: the companies that manufacture medicines used in the treatment of drug misuse
- Primary Care Trusts
- DH and Welsh Assembly Government.
 Stakeholders have been involved in the guideline's development at the following points:
- commenting on the initial scope of the guideline and attending a briefing meeting held by NICE
- contributing possible clinical questions and lists of evidence to the GDG
- commenting on the draft of the guideline.

4.8 VALIDATION OF THIS GUIDELINE

Registered stakeholders had an opportunity to comment on the draft guideline, which was posted on the NICE website during the consultation period. The GRP also

Methods used to develop this guideline

reviewed the guideline and checked that stakeholders' comments had been addressed.

Following the consultation period, the GDG finalised the recommendations and the NCCMH produced the final documents. These were then submitted to NICE. NICE then formally approved the guideline and issued its guidance to the NHS in England and Wales.

5. SERVICE USER INVOLVEMENT AND EXPERIENCE, AND IMPACT ON CARERS

5.1 INTRODUCTION

This chapter first offers a brief historical overview of service-user organisations and the ways in which these organisations have intersected with and influenced drug treatment services, in particular the contribution they are able to make to the development and provision of services. The second part of the chapter describes some people's experiences of drug services and the final section looks at the impact of drug misuse on carers.

The way that organisations for people who misuse drugs have become involved in services reflects a general intention in health and social care to take greater account of service user experience in shaping the development of services. With evidence that patient and public involvement improves outcomes, service delivery and planning (DH, 2004b), services are increasing their collaboration with service user organisations, individuals and carers.

5.2 HISTORICAL PERSPECTIVES OF SERVICE USER INVOLVEMENT

5.2.1 12-step fellowships

The 12-step fellowships of Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) largely predate the existing drug treatment field as a medical specialism. AA was founded in the US in 1935 and in the UK in 1947. NA was founded in the US in 1953, and the first UK meeting was held in 1980 (White, 1998).

Although these fellowships are user-led organisations that are concerned with the treatment and recovery of people with a drug problem, they also provide a form of treatment in itself – a pathway to recovery, which may be employed on its own, or as an adjunct to more formal treatment, as used in the Minnesota Model (Kelly, 2003).

Until quite recently, people who misuse drugs who had an association with the 12-step model tended to avoid the wider service-user movement. There are a number of possible reasons for this. The notion of anonymity is a core concept in the 12-step fellowships and some members feel that open involvement with service-user groups can seriously jeopardise their anonymity. Such concerns are often expressed alongside worries about the potential for relapse in these circumstances,

because members inevitably come into contact with people who actively misuse illegal drugs.

Nevertheless, there have been voices within the 12-step fellowships suggesting that wider involvement in service-user organisations is possible without breaching the 12 traditions, and this idea appears to be gaining some support (White, 2000), with an increase in people with a 12-step background actively engaging in other user organisations. The extent to which this collaboration is successful appears to depend on the experience and sophistication of those who are facilitating these events. Despite the points of conflict between people recovering from dependency and people who are actively using, when facilitators are able to keep participants focused upon common goals, members of these two groups have been able to work together effectively. An example where this collaborative working has flourished is the 'Experts by Experience' programme, established in 1993. Now funded by the NTA and facilitated by the National Institute for Mental Health in England, this project has sought to build the skill levels of service users and ex-users who are involved in service-improvement programmes.

5.2.2 Residential rehabilitation centres

Concept houses, a form of residential rehabilitation programme organised around a single 'big idea' or 'concept', grew out of AA. They were first developed by an organisation called Synanon, founded in the mid-1950s by Charles Dederich. A member of AA, Dederich was concerned about the number of drug-dependent people turning up at AA meetings who were being turned away.

Although Dederich and Synanon later fell into disrepute, some rehabilitation centres in the US based their programmes on the concept house's model of addiction and its theory and practice of treatment, namely confrontation and 'attack therapy'. At their most extreme, some rehabilitation centres required prospective residents to get on their knees and beg to be admitted as an indicator of their motivation. The encounter group became the basic treatment modality for rehabilitation programmes, in which residents were expected to 'confront' others about their behaviour. Failure to do so was regarded as a sign of relapse. Residents were forced to wear humiliating signs around their necks in order to address some psychological flaw, whether real or imagined. Some services recruited staff from former residents.

The treatment programmes' methods and philosophy gradually changed in the late 1980s and 1990s due to societal shifts, increasing evidence of the effectiveness of alternative treatments, and an improved understanding of drug misuse.

Rehabilitation centres in the UK are now judged to be a central component in the care pathway for people seeking a route out of dependence, with abstinence as the primary goal (NTA, 2006b). Residential services, providing 12-step programmes and therapeutic communities, offer psychosocial support and structured and intensive programmes of activities (see Chapter 9).

5.2.3 The birth and development of user involvement in harm reduction and maintenance therapy services: the 1980s and 1990s

Current user involvement in harm reduction and maintenance therapy services developed to some extent as a reaction against drug treatment centres. In the 1970s, problems reported by service users in rehabilitation centres could include:

- inappropriate and sometimes coercive or punitive treatment regimes for chronic dependence
- 'encounter' group sessions, where vulnerable women with a history of sexual abuse were 'confronted' about their sexuality by a room full of men
- vulnerable people being ejected from rehabilitation centres with no means of support.

In large areas of the UK there were also problems with outpatient treatment. Treatment varied significantly in different clinics; in some, high doses of opioids were dispensed without titration; in others, methadone maintenance was unavailable. Twenty-eight-day detoxification programmes were common, and so people went through repeated and often unsuccessful detoxifications in an attempt to stay away from the black market and criminal convictions for as long as possible. Prior to 1987, there were still large areas of the country where no specialist drug treatment was available.

These limitations of the services were a powerful impetus to the user movement, the first signs of which became apparent in the mid-1980s. One major catalyst was the publication of a number of articles by New York researcher Sam Friedman, who had been working in Holland and had become aware of the work of Nico Adriaans and the Rotterdam 'Junkiebond' or Addicts' Union (Friedman *et al.*, 1987). In the early 1980s, Adriaans and his group distributed clean syringes and needles throughout the streets and dealing spots of Rotterdam in response to an outbreak of what would later be identified as hepatitis C.⁵ With the advent of HIV and AIDS, their work became even more critical. As a consequence of this work, they were regularly consulted by the local police and the city council on policy matters and by the university, which employed them as fieldworkers/research assistants. The idea spread to Amsterdam and various groups made the case for a national Junkiebond (Trautmann, 2006).

In the UK, the arrival of HIV and AIDS meant that the public-health priority shifted, and the prevention of infection became more important than the achievement of abstinence. Some ex-users who were working in the drug treatment field found that the new model of 'harm reduction' gave them the opportunity to articulate a different, more pragmatic model of drug treatment. At the first International Conference on the Reduction of Drug-Related Harm, held in Liverpool in 1990, user involvement

⁵Hepatitis C was discovered in the early 1980s but was referred to as 'non-A non-B hepatitis'; only in 1989 was it properly identified as hepatitis C. Screening for it was developed in 1991 (http://www.hepcuk.info/data/usercontentroot/home/hepatitis%20c/Introduction.asp).

became a critical part of the harm reduction agenda (O'Hare *et al.*, 1992). A number of other groups emerged at this time in the UK. They included:

- Drug Dependents Anonymous (DDA), a charity whose goals were to help drug users and their families. The charity's board of trustees was a balance of users, families and other sympathetic local people. DDA engaged in a wide range of activities, including needle exchange, advocacy in treatment disputes, outreach work and community liaison (DDA, 1989).
- Mainliners, another user-led organisation, was originally established in 1990 as a self-help and advocacy organisation for intravenous drug users living with HIV. It rapidly gained a national profile in its original form as a user-led charity, but after reorganisation it followed the trajectory of the residential rehabilitation sector, as professional drugs workers were employed and the organisation became a standard tier-2 drug treatment provider.

By the mid 1990s, the idea of user involvement in harm reduction and maintenance therapy services was becoming part of the common parlance of drug treatment, although there was no unifying force or organisation in the UK. If there was a single event that solidified the idea of service-user involvement in these services as a viable and coherent notion, it was an international meeting of a pan-European group of service users. This meeting brought together representatives of user groups from across Europe and put together a position paper on the human rights of drug users in light of the AIDS epidemic, which was presented to the WHO and the European Commission.

This was to be the high point of user involvement in harm reduction and maintenance therapy services in the 1990s, however; throughout the rest of the decade, userled organisations and user involvement in general were in decline. Part of the reason for this was the nature of drug dependence as an illegal and highly stigmatised activity. The small group of users who had the skills and experience that would enable them to be effective in user-involvement activities tended also to have careers that they were reluctant to put at risk by identifying themselves as people who misuse drugs.

More recently there has been an emphasis on coalition working, in which people who misuse drugs and workers collaborate to achieve a common goal. Here a notable success has been the UK Harm Reduction Alliance, a group of clinicians, researchers and service users who are committed to raising the profile of the harm reduction agenda in drug treatment and drug policy (UK Harm Reduction Alliance, 2006). Other examples include the work of Edith Springer with the Clinton Peer AIDS Education Coalition (a group of sex workers and treatment providers who became AIDS activists) and Crew 2000, a peer coalition aimed at drugs education and harm reduction around dance drugs in Edinburgh (McDermott *et al.*, 1993).

5.2.4 User involvement today

Two groups, both of which had aspirations to be national drug-user organisations, emerged towards the end of the 1990s and were headed by drug users with a long history of working in the drug treatment field.

The first of these was the National Drug Users Development Agency (NDUDA) (Southwell, 2002). The NDUDA aspired to be a central development organisation that would coordinate and help in the development of all local user-involvement projects. With initial funding from Comic Relief, the NDUDA was also able to help local groups to obtain small grants that would be sufficient to establish them in their area. The current user involvement movement can be said to have evolved out of the NDUDA.

The second, established at the same time as the NDUDA, was the Methadone Alliance (Methadone Alliance, 2006), which sought to emulate the work of the US organisation, the National Alliance of Methadone Advocates, the primary goal of which was to advocate better treatment for people receiving methadone maintenance treatment.

The NDUDA and the Methadone Alliance had entered into an informal non-compete agreement. The NDUDA would act as the focal point of all user groups in the UK, while the Methadone Alliance would specialise solely in advocacy needs. The Methadone Alliance later became the Alliance, following a request from the NTA that it become more responsive to people with advocacy needs in all areas of drug treatment. The Alliance has recently secured funding from the Department of Health to enable it to employ six regional advocates, thus securing national coverage. However, 2 years after being funded by the NTA, organisational and management problems led to the collapse of the NDUDA.

In 2002, the Audit Commission completed its assessment of drug treatment in the UK and its findings echoed some of the views of people who had been involved with the user movement. The Audit Commission found that:

- people had difficulty accessing drug treatment services in the UK
- there were long waiting times and limited options for treatment
- there was a lack of staff training and expertise
- treatment did not always follow good practice
- there was suboptimal dosing for patients receiving pharmacotherapy (Audit Commission, 2002).

Perhaps in anticipation of this report, the government established the NTA in 2001. The NTA is a special health authority tasked with increasing the availability of drug treatment in the UK and with improving its quality. From the very beginning, the NTA embraced user involvement as a core component of its strategy for improving drug treatment in the UK (Best *et al.*, 2006). By doing so, the NTA has managed to make user involvement an integral part of the drug treatment landscape in the UK. Since its foundation, the NTA has:

- established the National Users Advisory Group
- created a user forum in each of the nine NTA regions
- ensured that service user involvement is a component of each of the NTA's activities at every level, including representation on the NTA board
- issued guidance to local providers and drug action teams on how to implement user involvement projects
- made progress on user involvement one of its performance indicators for local drug action teams.

Despite its achievements, the NTA's efforts in the user involvement arena have been criticised by some (Audit Commission, 2004). A subsequent follow-up report in 2004 by the Audit Commission suggested that the drug treatment field needed to improve its user focus and put in place a strategy that provided:

- a system for incorporating user and carer views into the development of national policy
- effective national and regional structures that involve users and carers in planning and performance management
- easy access to the wealth of advice on community and user engagement and opportunities for peer support (Audit Commission, 2004).

More recently a new national user organisation, the National User Network was established to replace the NTA's National User Advisory Group in response to the regionalisation of many of the NTA's functions. This organisation is expected to fulfil a similar role to that originally envisaged for the NDUDA.

Service user involvement in drug treatment has developed considerably in the UK. Twelve-step treatments have traditionally taken account of service users' experiences and are indeed based on them (see Chapter 8). More recently, harm reduction and maintenance-oriented services have involved service user organisations. User groups now exist in most areas of the UK, though they remain patchy in many, and they still face many challenges, which are predominantly developmental and resource focused. However, the principle is now firmly established within the drug treatment field.

5.3 SERVICE USER EXPERIENCE OF SERVICES

This section provides an overview of 'treatment journeys' based both on interviews conducted by Salter and colleagues (2005) and excerpts taken from personal stories on the WIRED website (http://www.wiredinitiative.com/research-addiction.htm). It reviews experiences of inpatient treatment and service user perceptions of abstinence and maintenance.

5.3.1 Treatment journeys

Salter and colleagues (2005) conducted semi-structured interviews with 15 service users regarding their experiences of dependence and recovery. The sample comprised individuals either in treatment or those using aftercare services. A grounded theory analysis was performed, from which seven dominant themes emerged: the nature of dependence and its development, the reasons/factors for use, the negative effects of use, the process of realisation, behaviour change, treatment and recovery. While it is helpful to identify common themes that emerge, treatment journeys are highly individual experiences and it should be borne in mind that the following is based on experiences from only 15 service users.

Reasons for use

In the sample, initial contact and experimentation with drugs were attributed to social pressure ('We always used to try everything together'; 'I wanted to be part of something') and as an aid to dealing with personal circumstances such as bereavement ('[heroin] took everything away'). The decision to continue using was associated with the search for a 'buzz', but this eventually led towards more excessive use in order to avoid withdrawal symptoms:

'It becomes a need. It changes from a craving to a complete obsession where you are thinking about it constantly'.

'The most important thing on your mind is to make yourself better so the first thing you do is go out and score'.

'I don't want to be turkeying, so I'm going to keep taking these drugs...as long as I've had my drugs in the morning I can still do a day's work'.

Nature of dependence

A common theme emerging in the personal accounts was that individuals experienced a rapid acceleration in their drug misuse that eventually led to them feeling 'controlled' by the drug. There was also some recognition of drug misuse as a 'disease':

"... It just spiralled out of control; it just went mad".

'The disease can take over and control you, manipulate you as a person. And you can manipulate others around you when you're under the influence of alcohol or drugs; it's very, very powerful...'

'There was no way out...I could see no way out of this...I felt there was absolutely nothing I could do; I thought I was going to die...'

Service users acknowledged that heroin in particular is a highly addictive drug, although many initially reported not knowing this: 'It's taken me until now to realise how powerful addiction is'.

Negative effects of misuse

The personal accounts suggested that drug misuse affects the individual in a number of negative ways: it can lead to physical and emotional/psychological problems, breakdown in relationships, social exclusion and employment difficulties.

Physical effects

Although physical health problems are common in people who misuse drugs, the need for the drug may militate against any concerns the individual may have about his or her health:

'I knew that I was ill. My chest was killing and I had a constant cough, but I didn't care'.

'The main thing is physically I have days where I wake up and I feel like I've done 10 rounds with Mike Tyson; my body feels totally battered, aching all over'.

Emotional/psychological effects

The testimonies suggest that some people misuse drugs as a means of coping with emotional or psychological problems, only to find that this exacerbates the problem:

'My mental health suffered as well. As long as I was blocking stuff out with the substance, I wasn't dealing with it, so the problems were getting worse all the time. It's not that it's not getting better, it's getting worse'.

'You don't have emotions when you're on gear. Emotions don't even come into the equation'.

Relationships and social exclusion

Long-term drug use can have devastating effects upon the family, leading to the individual feeling excluded from the family unit or culminating in him or her leaving home:

'It's really hurt my family. My mum washed her hands of me, saying "we've done everything we can for him and he doesn't want to help himself".

Not understanding the nature of dependence may cause the person who misuses drugs to feel that he or she is the only person with a problem:

'I felt isolated; I thought I was the only one who ever felt the way I felt. I thought that nobody could understand me'.

Within drug communities, there may also be a sense of isolation:

'Gear causes a lot of arguments and you end up falling out with everybody...you become really greedy; you don't want to share with your mates. I became really selfish'.

Employment

Long-term drug misuse may cause serious employment problems, leading to unemployment or preventing the person from finding a job:

'I was always in the manager's office. I started to take every Monday off, a long weekend, then I started to take every Friday off... and then I ended going in two days a week, and the rest of the time getting stoned'.

Process of realisation about dependence

In the early stages of dependence, service users were unaware of their dependence or chose to ignore it:

'I didn't see it as a problem; it was other people around me that saw it as a problem'.

'I knew inside that I had a problem, but I didn't want to admit it so I just carried on'.

Some individuals only came to realise the true extent of their dependence when they experienced withdrawal symptoms; however, this did not necessarily result in acceptance of the problem:

'I remember the day of having physical withdrawals and that's when I knew I needed it'.

'It dawned on me that I had a problem, but finding the solution didn't really come until my parents found out'.

Recognition of the problem can also occur as the dependence progresses:

'The deeper into my addiction I've got, the more I've realised I have a problem.'

'I completely blocked things out. It's only now that I'm in rehab that I've got a clear head to be able handle what was going on then. At the time, I tried hard not to think about it -I just used more and more'.

Acceptance of the problem came to many when their drug misuse adversely affected members of their family and, in particular, their children:

'I was doing it 50-50 for myself and my parents. I didn't want to have to put them through any more and I could see the state of myself'.

'I was getting to realise that I didn't really know my family any more and that I must have spent longer away from them and a lot longer off my face on one thing or another... I started to notice that gradually and then it hit me full on since I've been in [treatment]; I realised that I was losing touch with them'.

Behaviour change

A common theme emerging from the personal accounts was that individuals felt that they had to reach a crisis point before engaging in behaviour change:

'You've just got to hit rock bottom basically before you decide that you've got to stop doing this to yourself'.

'I couldn't go any lower; the only way was up'.

'I had to get out of injecting it because I knew that I would die'.

Some patients reached a stage whereby treatment was the only option:

'I was too ill not to go [for treatment]...'

Treatment

Many participants perceived treatment to be an opportunity for a fresh start:

'It gives you a chance to start again; you've got a new chance at life now to start again from scratch...I'm going back to college, getting my own place, getting a job... and starting again...'

Some individuals were aware that they needed to be ready and motivated to access treatment in order for it to be effective:

'You have to actually seek treatment. It's up to them if they want to start... If a person's not ready, they're not ready'.

'My true feeling is that you have to do it for yourself'.

However, participants perceived the long waiting times to be an obstacle in accessing treatment:

'I'd go with all the intentions to get off it... but the longer you have to wait, the more and more trouble you get in. Eight months is a long time; you don't know what is going to happen to you'.

Participants reported that, once they accessed treatment, they became more aware of their dependence as a problem and began to ask for help, which facilitated recovery:

'I've been taught to empty your closet...that's one thing I've never done is gone up to somebody and told them my problems...now I'm learning to go and ask for help. It's not that bad asking for help; it's not going to kill you'.

During treatment, participants were able to learn about the nature of their dependence and how to alter their drug-using lifestyles in order to deter further drug misuse:

'I've come here to learn how to deal with these problems without having to turn to drugs'.

'I've learnt how it all works for you – how it makes your body and how it makes you feel'.

Participants were also aware that treatment requires active engagement and a complete change in mindset:

'You get out of it what you put in. If you don't put anything in, you don't get anything out'.

'You've got to be willing to change everything – your behaviour, your thought patterns. It's not just about putting a drink or drug down, it's about changing your life'.

Recovery

Treatment was perceived as a crucial tool aiding recovery as it provides a 'safe' area, in which participants can meet people in similar situations, and therefore reduces isolation:

'I needed treatment. I tried to do it myself and it just didn't work and I felt very alone doing it myself because I couldn't really talk to people about how I was feeling and how awful I felt...they've not been in the same boat and they don't understand...'

5.3.2 Access to help and services, and early contact

The following extracts are taken from personal stories on the WIRED website (http://www.wiredinitiative.com/research-addiction.htm) and demonstrate that, although treatment can successfully reduce drug use and lead to abstinence, some service users reported that they did not receive adequate help when trying to access services:

'I went to every doctor's... everywhere. But we're smack heads, "See the door, close it on the way out, fuck off". That's all we got... them days... I was asking for methadone, that was all. I wasn't asking for valies [valium] or temazies [temazepam] or anything... You get sick of asking for help and not getting any'.

Service users expressed concern over the delay in accessing treatment and how this can lead to criminal behaviour, return to drug misuse and can have a negative impact on seeking further treatment:

'In them days, you'd have to wait up to a year for help and in that time you could have stolen millions of pounds' worth of items'.

'I was trying to get help from loads of drug agencies and they were like, "Sorry, we can't help you for 4 months, we've already got people on our books". I thought "I can't carry on like this for 4 months, it's going to be easier to end it". I think that's what one of the big problems is. Help not being available, when you need it. There were times where I'd get into a really bad way, try and get help and couldn't get it. And then when the help comes around you've usually got a bit of money and you think, 'I'm not ready to quit now'.

'I've been waiting to change for a long time, especially the last 2 years. We're all crying out for help and people just think if they give you a methadone script you'll shut up and go away, but it ain't that easy... And then you're like "Oh yeah, I'll have a bit of gear, one bit won't hurt." But it's never just one, is it?... You ask anyone'.

It was not uncommon for service users to report being unaware of treatment facilities open to them. In some cases, the person or his or her family would be the ones who actively sought out options:

'Even going to the doctors, you'd walk in and, as soon as you told them what the problem was, they'd have you out the door. It dawned on me that I had a problem, but finding the solution didn't really come until my parents found out'. [After hours of 'trawling' through the Yellow Pages, Stephen's parents contacted the NHS helpline, which put them in touch with a local drug agency.]

Accessing treatment in the prison setting was perceived by some service users as problematic due to their experience that little help or support was offered and hearing that:

'CARAT [counselling, advice, referral, assessment and throughcare] workers' visits were infrequent and not very helpful'.

However, for others the prison setting was seen as a fast-track to accessing services:

'I reached the point where he believed prison was the "best bet" because of the strict routine imposed there'.

Due to the strain on resources and limited spaces available in different treatment settings, some patients experienced being turned away from services:

'I really thought I was going to get off it, but I was told that I was going to have to wait a month for an appointment. When I went for that appointment they said I wasn't on it too badly so there wasn't a rush for me to be seen; it was going to take over 6 months'.

Conversely, for some service users the obstacle to accessing treatment was fear of involving social services with regard to their children:

'I used to work around the children so that I could pick them up from school and make dinner and things like that... I was worried what would happen to the children if I went to get help... so I just stayed on it, so I could get up in the morning and get the kids to school'.

5.3.3 Inpatient treatment

There is very limited research on the perceptions of people who misuse drugs of inpatient programmes and therapeutic aspects of treatment (Bacchus et al., 1999). Through semi-structured interviews with 42 people who misuse drugs receiving inpatient treatment, Bacchus and colleagues (1999) found that service users acknowledged the high demand for the service and were therefore generally satisfied with pre-admittance waiting times. However, some reported that, during the waiting period, their motivation to cease drug misuse decreased, and continued exposure to drug-misusing friends increased social pressure to maintain use. Service users - and especially parents who misuse drugs wished to receive more support and visits from family, though some felt the treatment environment was not appropriate for their young children. Most were able to develop a rapport with their keyworker, which motivated service users to achieve or maintain abstinence for fear of letting him or her down. Befriending and supporting other new service users was also conducive to abstinence maintenance and increased self-esteem, and the independent thinking involved in this role often operated as a marker of self-improvement. Attending an inpatient service also offered opportunities for self-reflection and reassessment. Sixty two percent of service users had made prior arrangements for aftercare, thus demonstrating their desire to maintain abstinence (Bacchus et al., 1999).

5.3.4 Service user perceptions of abstinence and maintenance treatment

Several authors have investigated the perceptions of people who misuse drugs of treatment services, their opinions of healthcare delivery and reasons for seeking treatment. McKegany and colleagues (2004) explored drug users' reasons for seeking treatment: specifically, whether treatment was sought to reduce risk behaviour or to become abstinent from drug use. Eighty-two per cent of the sample cited becoming abstinent and achieving stabilisation as their aim, with 57% attending a drug agency primarily to achieve abstinence. Patients expressed a preference for non-methadone drugs, thereby further demonstrating their desire to become abstinent. Very few people who misuse drugs cited harm-reduction outcomes, such as reduced use, stabilisation or safer use, as the only change they desired. This suggests that people who misuse drugs who approach treatment services have reached a stage whereby they no longer want to misuse drugs. Similar results were reported in the NTA service user satisfaction survey conducted in 2005. This revealed that users of prescribed methadone were more likely, when compared with users of heroin, cocaine and crack cocaine, to be satisfied with their level of use, but 50% wanted to stop completely and just over 10% wanted to reduce their use (Best *et al.*, 2006).

A self-report questionnaire administered by Clark and Wilkes (1997) found that, of a sample of 70 drug misusing service users, the primary reason for seeking help was being 'fed up' with using (78%), followed by concerns for family (72%), money worries (61%) and health problems (57%). These findings suggest that, after a certain length of drug misuse, service users become frustrated with their lifestyles and seek treatment to change their current behaviour. This sample was comprised of individuals receiving methadone maintenance. Thus, the most frequently desired service was receiving methadone prescriptions, and 82% reported being satisfied with the service they were receiving. However, 20% of the sample did express a wish to receive a quick detoxification, which suggests that some methadone users would rather achieve total abstinence than be maintained on methadone (Clark & Wilkes, 1997).

A significant proportion of people who misuse drugs in the UK currently receives methadone maintenance treatment, and therefore it is important to examine users' perceptions of the effectiveness of such treatment. Neale (1998) conducted semi-structured, qualitative in-depth interviews with 80 people who misuse drugs currently receiving prescribed methadone. Service users expressed mixed views on methadone: 45% felt that prescribed methadone had improved their emotional and physical well-being in terms of a reduction in painful withdrawal symptoms, and sleep facilitation. However, a similar percentage (43%) also reported experiencing negative health effects while on methadone, in particular damaged teeth, weight problems (gains or losses), stiffness and soreness. Moreover, there was widespread recognition that methadone is simply a substitution of one drug (heroin) for another highly addictive substance that produces similarly bad withdrawal symptoms when people attempt to discontinue use (Neale, 1998). Another common criticism was that being on methadone scripts is very time-consuming, as the script must be collected on a daily basis. For many, this restricts the opportunity to perform a regular job. Conversely, while employment opportunities are not necessarily enhanced, people perceive themselves to be in a better financial situation as they may no longer have to sell their personal belongings or accrue debts to finance an illicit drug habit.

5.4 ADDRESSING THE NEEDS OF FAMILIES AND CARERS

There is an increasing recognition that drug misuse affects the entire family and the communities in which these families live. The NTA user satisfaction survey found that 25% of respondents felt that staff did not offer families and carers enough support (Best *et al.*, 2006). The Home Office's updated drug strategy (Home Office, 2002) includes targets on increasing access to help, advice and counselling for parents, carers and families of people who misuse drugs. Staff should be particularly aware of the needs of children (ACMD, 2003 & 2007) and consider their own responsibility under the Children Act (1989).

There has also been a growth in organisations for carers of people who misuse drugs, most notably Adfam and Families Anonymous (FA), and over 100 peer-support family groups in the UK have been founded on parents' own experience of drug misuse in their families. Adfam evolved in the mid 1980s after a distressed mother of a drug user found that there were no support services to assist and advise her regarding her child's drug problem. The main ethos of the service is to provide support, training and advocacy for families of drug and alcohol users. It also informs the government about patient and family needs and challenges policy makers, decision makers and the media to better represent and understand the issues facing families of people who misuse drugs. Adfam has undergone marked development over the past two decades; it provided a nationwide helpline service (which closed in 2002), added training and criminal justice work to the service in the 1990s and recently expanded its community development team.

FA is a self-help service based on the 12-steps and is aimed at helping families affected by drug misuse and behavioural problems. Families attend meetings on a regular basis and share their experiences with other families. Through these meetings family members are able to support one another and overcome some of the issues they face. Families also learn that their behaviour may enable people who misuse drugs to persist in drug misuse; for example, protecting that person from the consequences of dependence may encourage him or her to continue negative drug behaviours. FA originated in Los Angeles in 1971 and was introduced to the UK in 1980. Like Adfam, it has also expanded in recent years, with approximately 50 groups running throughout the UK at present, and has services worldwide.

Despite the recognition of carers' needs and the growth of carer organisations, however, there is a rather limited evidence base assessing the impact on carers and families of people who misuse drugs and on interventions intended to support them, and even less attention given to the needs of families and carers in their own right. Most interventions have targeted carers and families primarily to improve outcomes for the person who misuses drugs and only secondarily to address the needs of the family/carer. Bancroft and colleagues (2002) noted that there is a division in the literature between those who consider drug misuse 'a problem *for* the family' and those who consider it 'a problem *of* the family'. Taking the latter approach may result in the carer or family member feeling stigmatised and less likely to seek professional help.

There is a need to assess the impact on family members and carers of people who misuse drugs in order to identify the challenges they face and to evaluate the most effective ways to offer help and support to them. Velleman and colleagues' (1993) report of 50 close relatives of people who misuse drugs suggested a strong impact on families and carers, which is both psychological (for example, feelings of loneliness, isolation, anxiety and depression) and physical (including raised blood pressure, ulcers, and so on). Hudson and colleagues (2002) assessed the social adjustment of 65 female family members and significant others of people who misuse drugs using the Social Adjustment Scale – Self-Report (SAS-SR; Weismann & Bothwell, 1976). They compared SAS-SR scores for family members and significant others of people who misuse drugs with 'standard' control conditions derived from two other published studies (Rorty et al., 1999; Weissman et al., 1978). Family members and significant others of people who misuse drugs were found to have greater difficulties in relation to social, work, social/leisure and extended family adjustment than a 'standard' comparison group. However, the rather problematic nature of the comparison group (derived from other studies with clear geographical and temporal differences) limits the ability to make a genuine comparison between the two groups.

It appears the impact on family members may differ depending on the roles and responsibilities within the family. Lewis and Williams (1994), in their study of a family support group for African-American grandparents, found that grandparents often took the role of primary carer for their grandchildren because their children had difficulties fulfilling parental responsibilities, due to drug misuse, serving prison sentences, and so on. This sometimes resulted in financial problems as government funding for childcare was not always passed on to the grandparents. Velleman and colleagues (1993) found partners were more likely to report physical violence, threatening behaviour and pressure for money, while parents were more likely to report lying, manipulation and self-neglect by the person who misuses drugs. Hudson and colleagues (2002) also compared the experiences of partners and parents of people who misuse drugs and found that partners tended to have slightly greater adjustment problems than parents. The main difference appeared to be financial, with partners of people who misuse drugs experiencing greater financial problems than parents.

A report by Adfam (Sims, 2002) identified a number of needs for families of people who misuse drugs and alcohol. One of the most important of these reported by families was coping with stigma. It was argued that stigma was a major barrier in preventing carers or family members from accessing services, both in terms of actual exclusion from primary care services and self-exclusion through fear of being judged. A further need was to access services. Provision of services for families of people who misuse drugs was found to be rather limited (see also Bancroft *et al.*, 2002), but even where these services were available, many families were either not aware of them or how to access them. Many families also perceived themselves to be excluded from participation in the treatment provided for their family member. Some families felt that workers were hiding behind confidentiality when they could have provided general information about treatment.

5.4.1 Clinical practice recommendations

- 5.4.1.1 Staff should discuss with people who misuse drugs whether to involve their families and carers in their assessment and treatment plans. However, staff should ensure that the service user's right to confidentiality is respected.
- 5.4.1.2 Staff should ask families and carers about, and discuss concerns regarding, the impact of drug misuse on themselves and other family members, including children. Staff should also:
 - offer family members and carers an assessment of their personal, social and mental health needs
 - provide verbal and written information and advice on the impact of drug misuse on service users, families and carers.

6. IDENTIFICATION AND RECOGNITION

6.1 INTRODUCTION

6.1.1 Defining screening and identification

Screening has been defined as the systematic application of a test or enquiry to identify individuals at high risk of developing a specific disorder who may benefit from further investigation or preventative action (Peckham & Dezateux, 1998). Screening programmes detect people who have the condition or are at risk of developing the condition in the future. They do not establish a diagnosis but give some indication of any action that may be required, such as further diagnostic investigation, closer monitoring or even preventative action. Screening is not necessarily a benign process (Marteau, 1989). Since screening tools may never be 100% accurate, people who are incorrectly identified as being at risk of developing a condition (false positives) can be subject to further possibly intrusive, harmful or inappropriate investigations, management or treatment. Those falsely identified as not being at risk of developing a condition (false negatives) will also suffer by not being given the opportunity to undergo the further investigations that are needed.

The National Screening Committee (NSC), in its guidance for determining whether a national screening programme should be undertaken for any disorder, has set 22 criteria for appraising the viability, effectiveness and appropriateness of a programme for large population screening (NSC, 2003). These include: the need for a simple, safe, precise and validated screening test; an agreed policy on the further evaluation of individuals with a positive test result; the availability of an effective intervention for those identified through early detection, with evidence of early treatment leading to better outcomes than later treatment; adequate resources available prior to commencement; and acceptability to the population. It is important that the majority of these criteria are satisfied before a screening programme is adopted, not least because screening can cause adverse effects, including distress secondary to asking specific questions, raising concerns and raising expectations of care.

Existing NICE mental health guidelines have considered the case for general population screening for a number of mental health disorders and concluded that it should only occur for specific high-risk populations where benefits outweigh risks (for example, NICE, 2004a, 2005a).

Screening has two main functions: identification and prediction. For the purpose of this guideline, identification refers to the detection of current drug misuse. Prediction refers to the detection of risk factors, either current or past, that increase the probability of developing drug misuse. This chapter will only be addressing identification of current drug misuse, as prediction lies outside the current scope of the guideline (see Appendix 1).

Identification and recognition

Additionally, this chapter distinguishes between methods to identify drug misuse and tools used to provide comprehensive clinical assessment of drug misuse. The latter are again outside of the scope but are covered in greater detail in the NICE clinical guideline *Drug Misuse: Opioid Detoxification* (NICE, 2007).

Prevalence of drug use

As described in Chapter 3, the British Crime Survey 2005/6 (Roe & Man, 2006) estimated that 34.9% of 16-59 year olds had used one or more illicit drugs in their lifetime, 10.5% had used one or more in the previous year and 6.3% in the previous month. Cannabis was the most widely used drug; 8.7% of 16-59 year olds reported using this drug in the previous year. Cocaine was the next most commonly used drug; 2.4% reported using either cocaine powder or crack cocaine in the previous year. This was followed by ecstasy at 1.6% and amphetamines at 1.3%. Heroin use was much lower, with 0.1% reportedly using opiates in the past year. The large majority of these individuals does not present to drug treatment services, but does present to acute medical services, the criminal justice system and social care agencies, often as a consequence of the drug misuse (Crome et al., 2006). Effective methods of identifying people who misuse drugs therefore may have value in promoting access to appropriate treatment services. This chapter will not deal with the use of large-scale screening or identification tools in the workplace, schools and sport, which is beyond the scope of the guideline. It will be restricted to identification of at-risk populations in health, social care and criminal justice settings.

Current practice

Routine screening for drug misuse in the UK is largely restricted to criminal justice settings, including police custody and prisons (Matrix Research and Consultancy & NACRO, 2004). In health and social care settings, however, the use of methods for identification and recognition is sparse. Initiatives are under way to introduce routine or targeted screening for alcohol misuse in health and criminal justice settings as part of the National Alcohol Harm Reduction Strategy (Prime Minister's Strategy Unit, 2004) and public health strategy (DH, 2004a). A recent study of psychiatric inpatients in London found that only 1 in 50 patients admitted to a teaching hospital had undergone screening for drug misuse (Barnaby *et al.*, 2003). The updated Models of Care service framework emphasises the importance of non-specialist (tier 1) services in the identification of drug misuse as a precursor to referral for treatment (NTA, 2006a). However, most of these programmes are in the early stages of development and there is a clear need for improvement of identification methods for drug misuse in the UK.

6.2 IDENTIFICATION TOOLS

There are a range of tools for identifying drug misuse, including routine clinical enquiry (where the clinician asks questions about whether an individual uses drugs and, if appropriate, frequency and consequences of this use), questionnaires (paper-and-pencil tests, based either on clinician rating or self-report, to assess whether an

individual meets certain criteria for dependence or misuse of drugs) and biological testing (testing of urine, oral fluid or hair samples to assess whether a person has used certain drugs within a certain period of time).

The key measures of effectiveness of a drug misuse identification instrument are generally considered to be sensitivity (the probability that someone with drug dependence will have tested positive), specificity (the probability that someone without drug dependence will have tested negative), the positive predictive value (the probability that someone with a positive test result will receive a diagnosis of drug dependence), the negative predictive value (the probability that someone with a negative test result will not receive a diagnosis of drug dependence) and overall efficiency (percentage of cases correctly classified by the test as being or not being dependent). A good test will have reliable results on all these different measures. The relative value placed on each measure in determining which test to use is based on several factors, including the prevalence of the disorder among the group being considered and the risks of missing a diagnosis. It can be argued that the positive predictive value is of particular importance. As the prevalence of a condition reduces, so does the positive predictive value; that is, there are more individuals who screen positive but do not have the condition (false positives).

6.2.1 Identification questionnaires

Several identification questionnaires have been developed to identify drug misuse. These may be of potential use for identifying drug misuse in at-risk populations. Only questionnaires of fewer than 30 items, validated against a structured interview that yielded a diagnosis of drug misuse/dependence, were included in this review. Eight studies reviewed below met the eligibility criteria. These studies were evaluated in terms of psychometric effectiveness (sensitivity, specificity, positive predictive value and negative predictive value); feasibility for use in health, social and criminal justice settings; and relevance to UK context.

Clinician-rated questionnaires for adult populations

The Drug Use Disorders Identification Test (DUDIT; Berman *et al.*, 2005) is based on the WHO's validated and widely used Alcohol Use Disorders Identification Test (AUDIT; Babor *et al.*, 2001). DUDIT consists of 11 clinician-rated items covering domains of drug consumption, dependence and problems associated with use. It has been validated in a Swedish drug-using population, and in that context had an acceptable level of sensitivity (90%) but not specificity (78%) (Berman *et al.*, 2005).

The CAGE questionnaire has been adapted to include drugs (CAGE-AID; Brown & Rounds, 1995). CAGE was originally developed to identify alcohol misuse and in that context has acceptable sensitivity and specificity. However, among a general hospital population, three of the four items of the clinician-rated CAGE-AID had fairly low sensitivity (71%) and specificity (76%) in relation to the detection of drug use (Brown *et al.*, 1998).

The Chemical Use Abuse and Dependency (CUAD) scale is clinician rated and has been developed and used in psychiatric populations (McGovern & Morrison,

1992). A validation study found high sensitivity (88%) and specificity (93%) (Appleby *et al.*, 1997). Also used in psychiatric populations is the Dartmouth Assessment of Lifestyle Instrument (DALI), an 18-item clinician-rated scale concerned mainly with alcohol, cocaine and cannabis use (Rosenberg *et al.*, 1998). The items for alcohol and drug use were analysed separately; the items designed to measure cannabis and cocaine use had a sensitivity of 80% and a specificity of 100%.

Of the questionnaires discussed above, DUDIT had the highest sensitivity and specificity and was also relatively quick to administer (11 items). However, this has not been validated outside of a known drug-using population and would require further research before it can be recommended for general use in the UK. It is also important to note that most of the other questionnaires have only been studied in North American psychiatric populations and their validity in other settings is unknown.

Clinician-rated questionnaires for adolescent populations

The only questionnaire identified was CRAFFT (Knight *et al.*, 1999). This is a nineitem measure developed to identify drug misuse for 14–18 year olds in an adolescent medical clinic. A cut-off score of two had a sensitivity of 92% and specificity of 82%. A follow-up study (Knight *et al.*, 2002) found similar results, with a sensitivity of 92% and specificity of 80%. However, positive predictive value was low (0.25), suggesting a high probability of false positives. This questionnaire has not been validated in a general clinical population administered by clinicians, and its properties in a UK adolescent population are unknown.

Self-report questionnaires for adult populations

The shorter variant of the Drug Abuse Screening Test (DAST-10) has been used as a self-report drug misuse screening tool in psychiatric populations (Carey *et al.*, 2003; Maisto *et al.*, 2000). Maisto and colleagues (2000) found that sensitivity ranged from 70–90% and specificity ranged from 67–80%, depending on the cut-off used. It is therefore not of value as an identification tool.

Self-report questionnaires for adolescents

The self-report DAST has been adapted for use in adolescent psychiatric populations (Martino *et al.*, 2000) with moderate sensitivity (79%) and specificity (85%). However, with 27 items, it is not likely to be feasible for use as an identification tool.

The Problem-Oriented Screening Instrument for Teenagers (POSIT; Latimer *et al.*, 2004) is a 17-item scale adapted from the 139-item POSIT. It does not have an acceptable level of sensitivity (77%), specificity (60%) or positive predictive value (19%).

There appear to be no feasible or psychometrically acceptable self-report identification questionnaires.

6.2.2 Biological testing

Urinalysis

Urinalysis remains the most reliable tool for identifying drug use in a drug-using population (National Academy of Clinical Biochemistry [NACB], 2006; DH, 2007).

George and Braithwaite's (2002) review of near-patient testing tools (including urine, oral fluid and hair analysis) suggested limited or variable sensitivity in detecting drug use. Similarly, such devices may be useful for the detection of short-term use of drugs but are not suitable for widespread routine use (DH, 2007). However, a recent targeted screening study by Tomaszewski and colleagues (2005) in a US emergency department found excellent sensitivity and specificity for opioid (sensitivity = 100%, specificity = 98.7%) and cocaine use (sensitivity = 96.8%, specificity = 99.3%) but lower sensitivity for cannabis use (sensitivity = 87.5%, specificity = 99.3%) when comparing near-patient urine testing with confirmatory laboratory tests.

Oral fluid analysis

The major advantages of oral fluid drug testing are that it is less intrusive than urinalysis and that oral fluid can be relatively easily obtained. These properties enable oral fluid testing to be conducted by personnel with relatively little training and make it less open to adulteration (DH, 2007).

Gronholm and Lillsunde (2001) found poor sensitivity for detecting benzodiazepines and cannabinoids. In a small study (n = 15) by Samyn and Van Haeren (2000), results obtained by law enforcement officers correlated well with laboratory results for cocaine and amphetamines but were unsatisfactory for detecting heroin and cannabis.

Although oral fluid testing is a reasonable alternative to urinalysis, there are several limitations. Firstly, oral fluid can only identify very recent consumption of drugs. Detection times for drugs in oral fluid are considerably shorter (5–48 hours) compared with 1.5–4 days in urine (Verstraete, 2004). Secondly, drug concentration can differ depending on the collection method. Stimulation of saliva flow is often used, which can be problematic as the pH for stimulated flow is approximately 8, compared with the basal saliva pH of 6.5. Therefore any drug with a pKa around these values will be substantially affected, possibly leading to decreased drug concentration (NACB, 2006). Thirdly, there is a lack of evidence on interference, oral drug residues and other issues of manipulation that may affect the validity of oral fluid analysis (NACB, 2006).

There is some evidence for the use of oral fluid as an alternative to urinalysis; however, the limitations of this testing method should be taken into account.

Hair analysis

The testing of human scalp hair for drug use has the potential for detecting drug use over a longer period than urine or oral fluid testing (DH, 2007). Hair analysis is also potentially less intrusive than urinalysis.

There are, however, a number of difficulties associated with the use of hair analysis. This form of testing is still in a period of development, with sufficient quality-control criteria yet to be established (DH, 2007). Therefore, hair analysis is associated with the need for a higher level of expertise and consequently there are greater costs involved. There is a lack of evidence to support widespread and routine use of hair analysis for the identification of drug use in at-risk populations.

6.2.3 Clinical summary

The development of questionnaire tools for identification of drug misuse is in its infancy in comparison with the equivalent methods for detection of alcohol misuse. Although some measures had reasonable sensitivity and specificity, the evidence base for this was often drawn only from one or at best two studies. The self-administered or clinician-administered measures are easier to administer than biological testing and probably more acceptable to service users but have weaker sensitivity and specificity and can be time-consuming to administer and score.

Urinalysis and oral fluid testing appear to be useful methods of identifying drug use; however, both testing matrices have associated problems. Urinalysis is not easy to administer as a routine identification instrument and has also low acceptability to service users in non-specialist healthcare settings, while oral fluid has a more limited window of opportunity for detecting drug use and there is limited research assessing possible interference or manipulation of samples. However, these two testing methods appear to be more easily implemented than hair analysis, which requires a great deal more expertise.

6.2.4 Clinical practice recommendations

Routine clinical questions

- 6.2.4.1 Staff in mental health and criminal justice settings (in which drug misuse is known to be prevalent) should ask service users routinely about recent legal and illicit drug use. The questions should include whether they have used drugs and, if so:
 - of what type and method of administration
 - in what quantity
 - how frequently.
- 6.2.4.2 In settings such as primary care, general hospitals and emergency departments, staff should consider asking people about recent drug use if they present with symptoms that suggest the possibility of drug misuse, for example:
 - acute chest pain in a young person
 - acute psychosis
 - mood and sleep disorders.

Biological tests

6.2.4.3 Healthcare professionals should use biological testing (for example, of urine or oral fluid samples) as part of a comprehensive assessment of drug use, but they should not rely on it as the sole method of diagnosis and assessment.

7. BRIEF INTERVENTIONS AND REDUCTION OF INJECTION AND SEXUAL RISK BEHAVIOURS

7.1 INTRODUCTION

Reducing drug-related harm is a widely cited aim in the treatment of people who misuse drugs (for example, DH, 1999; NTA, 2006a) and is relevant to all chapters in this guideline. This chapter concerns the use of brief interventions to reduce drug-related harm (focused on opioids, stimulants and cannabis) by encouraging abstinence and/or reduction of drug use. Additionally, drug misuse is often associated with increased injection and sexual risk behaviours. This chapter will also consider interventions designed to reduce such risk behaviours.

7.2 BRIEF INTERVENTIONS

7.2.1 Introduction

Brief interventions have a variety of potential advantages in the treatment of drug misuse, including ease of delivery and less difficulty associated with retaining people who misuse drugs. The provision of such interventions is better developed in the treatment and management of alcohol-related problems (SIGN, 2003). It should be noted that a significant proportion of people misusing opioids, stimulants and cannabis also misuse alcohol and this is reflected in the participants in some of the trials described below. Brief interventions can be conducted in a variety of settings, including non-medical settings, and can be given opportunistically to people not in formal drug treatment or as an adjunct to formal structured drug treatment (Ashton, 2005).

7.2.2 Definitions of interventions

Brief interventions are defined here as interventions with a maximum duration of two sessions. The main aim of the intervention is to enhance the possibility of change in terms of abstinence or the reduction of harmful behaviours associated with drug misuse. The principles of brief interventions include expressing empathy with the service user, not opposing resistance and offering feedback, with a focus on reducing

ambivalence about drug misuse and possible treatment. A number of brief interventions are based on principles drawn from motivational interviewing.

In the included studies reviewed below, brief interventions were compared with no treatment/minimal interventions and other active interventions. The minimal interventions mainly consisted of providing a self-help or information booklet on drug misuse. The active interventions included relapse-prevention CBT and, for people within formal treatment, standard care.

Relapse-prevention CBT focuses on helping drug users to develop skills to identify situations or states where they are most vulnerable to drug use, to avoid high-risk situations, and to use a range of cognitive and behavioural strategies to cope more effectively with these situations (Carroll & Onken, 2005).

Standard care for people in formal drug treatment ranged from methadone maintenance treatment to cocaine or opioid detoxification and relapse-prevention CBT.

7.2.3 Outcomes

The primary outcomes assessed were related to abstinence and drug use. Abstinence can be expressed in a variety of ways, but the two main measures examined were point abstinence and duration of abstinence. Measures of abstinence based on urinalysis were preferred but self-report measures were not excluded. Point abstinence refers to evidence for the absence of drug use at a particular point in time (for example, end of treatment or at 12-month follow-up). The main limitation of this measure is that, due to the relapsing nature of drug misuse, it is not necessarily indicative of abstinence over a longer period of time. For example, a person's abstinence at the end of treatment does not indicate whether he or she used drugs less during treatment than others who were not abstinent at the end of treatment. Therefore, a measure of the duration of abstinence over a period of time is also important to assess how long a person remains abstinent, and the proportion of days a person is abstinent over a period of time.

Frequency of illicit drug use is also an important measure because, although abstinence may be a desired goal, reducing the frequency of drug misuse may be a more realistic way of reducing drug-related harm. Drug misuse is usually measured by self-report, usually in terms of the frequency of using particular drugs over a period of time.

7.2.4 Current practice

Although brief interventions are considered to be an important component of psychosocial treatment in open-access drug services (for example, NTA, 2002, 2006a), provision of such interventions varies widely throughout England and Wales. They have been provided in evaluative studies in a range of settings, including inpatient psychiatric settings (Baker *et al.*, 2002), schools (Tait & Hulse, 2003), higher education (McCambridge & Strang, 2003) and general healthcare (Miller *et al.*, 2006), as well as in formal drug treatment services (Stotts *et al.*, 2001). Despite this work,

the precise extent of the use and distribution of these interventions is not well understood, but it is reasonable to assume that they are not widely implemented in the UK at the present time. This review considers, therefore, not only the efficacy of brief interventions but also the settings in which they are provided, so as to better understand the likely benefit for people who misuse drugs who are not in formal drug treatment, as well as those who are.

7.2.5 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 2.

Table 2: Databases searched and inclusion/exclusion criteria for clinical effectiveness of brief interventions

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	People who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	Brief interventions
Outcomes	Abstinence: point abstinence, duration of abstinence Illicit drug use

7.2.6 Studies considered⁶

The review team conducted a new systematic search for RCTs that assessed the efficacy of brief interventions.

For the stand-alone brief-intervention review for people not in formal drug treatment or for those seeking treatment, seven trials (BAKER2005; BERNSTEIN2005; COPELAND2001; MARSDEN2006; MCCAMBRIDGE2004; STEPHENS2000; STEPHENS2002) met the guideline eligibility criteria, providing data on 2,701

⁶Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

participants. All were published in peer-reviewed journals. In four trials brief interventions were assessed for people who misuse cannabis (COPELAND2001; MCCAMBRIDGE2004; STEPHENS2000; STEPHENS2002), in three trials for people who misuse stimulants (BAKER2005; BERNSTEIN2005; MARSDEN2006) and in one trial for people who misuse opioids (BERNSTEIN2005).

For the brief-intervention review for people within formal drug treatment, four trials (CARROLL2006A; MILLER2003; MITCHESON2007; STOTTS2001) met the guideline eligibility criteria, providing data on 625 participants. All trials were published in peer-reviewed journals. In all four trials brief interventions were assessed for people who misuse stimulants, in one trial for people who misuse cannabis (CARROLL2006A) and in one trial for people who misuse illicit opioids (MILLER2003).

For the review comparing brief interventions and relapse-prevention CBT, four trials (BAKER2005; COPELAND2001; STEPHENS2000; STEPHENS2002) met the guideline eligibility criteria, providing data on 807 participants. All of these were published in peer-reviewed journals. In three trials comparisons between brief interventions and relapse-prevention CBT were examined for people who misuse cannabis (COPELAND2001; STEPHENS2000; STEPHENS2002) and in one trial for people who misuse stimulants (BAKER2005).

In addition, nine studies were excluded from the analysis. The most common reason for exclusion was not providing required outcomes (further information about both included and excluded studies can be found in Appendix 14). The forest plots and full evidence profiles can be found in Appendix 15 and Appendix 16 respectively.

7.2.7 Stand-alone brief interventions for people who misuse drugs

This section assesses brief interventions for people who are not in formal drug treatment (for example, opportunistic interventions for people who are presenting for a physical health problem in primary care) and people who are not in drug treatment but who are seeking treatment for a drug problem.

Most studies were for people who misuse cannabis or stimulants, for whom brief interventions were associated with greater abstinence and reduced drug use compared with no treatment or minimal control groups across follow-up periods ranging from 3 to 12 months (see Table 3 for study information and Table 4 for the evidence summary). One trial conducted on people misusing opioids suggests brief interventions may also be effective for this group.

There were mixed results for comparisons of brief interventions with relapse-prevention CBT. For people who misuse cannabis, individual relapse-prevention CBT, but not group relapse-prevention CBT, appeared to be more effective than brief interventions, but it should be noted that the relapse-prevention CBT interventions provided in both trials had four times as many sessions as the brief intervention. For people who misuse stimulants (amphetamines), no differences were found between individual relapse-prevention CBT and brief interventions.

Continued

Table 3: Stu	udy information table for	dy information table for trials of stand-alone brief interventions for people who misuse drugs	terventions for people who	misuse drugs
	Brief intervention versus control for stimulants or opioids	Brief intervention versus control for cannabis	Individual relapse- prevention CBT versus brief intervention	Group relapse- prevention CBT versus brief intervention
Total no. of trials (total no. of participants)	3 RCTs (N = 1,268)	4 RCTs (1 cluster randomised) (N = 764)	3 RCTs $(N = 602)$	1 RCT (N = 205)
Study ID	BAKER2005 BERNSTEIN2005 MARSDEN2006	COPELAND2001 MCCAMBRIDGE 2004* STEPHENS2000 STEPHENS2002	BAKER2005 COPELAND2001 STEPHENS2002	STEPHENS2000
Problem drug or diagnosis	Cocaine: BERNSTEIN2005 MARSDEN2006 Crack cocaine: MARSDEN2006 Amphetamine: BAKER2005 Heroin: BERNSTEIN2005	Cannabis: MCCAMBRIDGE 2004 Cannabis (DSM-III-R/IV dependence): COPELAND2001 STEPHENS2000 STEPHENS2002	Amphetamine: BAKER2005 Cannabis: COPELAND2001 Cannabis (DSM-III-R/IV dependence): COPELAND2001 STEPHENS2002	Cannabis (DSM-IV): STEPHENS2000

Table 3: (Continued)

	Brief intervention versus control for stimulants or opioids	Brief intervention versus control for cannabis	Individual relapse- prevention CBT versus brief intervention	Group relapse- prevention CBT versus brief intervention
Baseline severity: mean (standard deviation [SD])	DAST score: 8.0 (BERNSTEIN2005) Years' regular amphetamine use: 8.98 (6.99); daily level amphetamine use (Opiate Treatment Index): 1.50 (1.65) (BAKER2005)	Years' weekly cannabis use: 13.9 (COPELAND 2001) Years' cannabis use: 17.35 (5.21); days of use in past 90 days: 74.64 (18.54) (STEPHENS 2000) Proportion days of use in past 90 days: 0.88 (STEPHENS 2002)	Years' regular amphetamine use: 8.98 (6.99); daily level amphetamine use (Opiate Treatment Index): 1.50 (1.65) (BAKER2005) Proportion days of use in past 90 days: 0.88 (STEPHENS2002)	Years' cannabis use: 17.35 (5.21); days of use in past 90 days: 74.64 (18.54) (STEPHENS2000)
Treatment length	1 session	2 sessions	CBT: 4 sessions (BAKER2005; COPELAND2001) 9 sessions (STEPHENS2002) Brief intervention: 1 session (BAKER2005), 2 sessions (COPELAND2001; STEPHENS2000)	CBT: 14 sessions Brief intervention: 2 sessions
Length of follow-up	6 months	Up to 12 months	Up to 12 months	16 months
Age (years)	32 to 36	16 to 38	30 to 36	34

*cluster randomised

Table 4: Summary evidence table for trials of stand-alone brief interventions for people who misuse drugs

	Brief intervention versus control for stimulants or opioids	Brief intervention versus control for cannabis	Individual relapse- prevention CBT versus brief intervention	Group relapse- prevention CBT versus brief intervention
Total no. of trials (total no. of participants)	3 RCTs $(N = 1,268)$	4 RCTs (1 cluster randomised) (N = 764)	$\frac{3 \text{ RCTs}}{(N = 602)}$	1 RCT (N = 205)
Study ID	BAKER2005 BERNSTEIN2005 MARSDEN2006	COPELAND2001 MCCAMBRIDGE 2004* STEPHENS2000 STEPHENS2002	BAKER2005 COPELAND2001 STEPHENS2002	STEPHENS2000
Evidence profile table number (Appendix 16)	Table A16-1	Table A16-1	Table A16-1	Table A16-1
Overall quality of evidence	High	Moderate	Moderate	Low

Continued

Table 4: (Continued)

	Brief intervention versus control for stimulants or opioids	Brief intervention versus control for cannabis	Individual relapse- prevention CBT versus brief intervention	Group relapse- prevention CBT versus brief intervention
Point abstinence	Stimulants 6-month follow-up: RR 1.30 (1.09 to 1.55), K = 3, N = 1,268 Heroin follow-up: RR 1.54 (1.09 to 2.16), K = 1, N = 1,175 Heroin and cocaine follow-up: RR = 1.45 (1.02 to 2.05), K = 1, N = 1,175	Continuous duration for cannabis: 3–4 months: RR 3.33 (1.99 to 5.56), K = 3, N = 613 Proportion days not using cannabis: 3-month follow-up: SMD -0.42 (-0.81 to -0.03), K = 1, N = 105 Continuous duration of abstinence for cannabis: 8–12 months: RR = 2.41 (-1.01 to 5.73), K = 2, N = 345	Cannabis follow-up: RR 2.60 (1.45 to 4.66) K = 2, N = 462 Follow-up: SMD 0.24 (-0.13 to 0.51), K = 1, N = 102 Amphetamine: RR 0.89 (0.57 to 1.39), K = 1, N = 140	
Drug use	Cannabis 3-month follow-up (adjusted for baseline differences): $B = 11.54 (6.91 \text{ to } 16.18)$, $p < 0.0001$, $K = 1$, $N = 200$	Cannabis 4-month follow-up: SMD -0.68 (-0.88 to -0.49), K = 2, N = 432	Cannabis 9-month follow-up: SMD -0.43 (-0.58 to -0.17), $K = 1$, $N = 245$	Cannabis 12-month follow-up: SMD 0.03 (-0.65 to 0.23), K = 1, N = 179

RR > 1 favours intervention; in comparisons of CBT and brief interventions RR > 1 favours CBT; negative SMD values favour intervention; in comparisons of CBT and brief interventions negative SMD values favour CBT; B > 1 favours intervention.

*Adjusted for clustering effects.

7.2.8 Adjunctive brief interventions versus standard care for people who misuse drugs and are receiving formal drug treatment

Brief interventions have also been assessed as an adjunct to formal drug treatment programmes. This section is concerned with whether such an additional intervention for people already engaged in formal treatment improves abstinence and drug-use outcomes.

The use of brief interventions as an adjunct to formal drug treatment did not have any important effects on drug use compared with standard care (see Table 5). MILLER2003 found no statistically significant differences between the brief intervention and standard care groups for days abstinent from illicit drugs or for treatment attendance. This finding was consistent for inpatient and outpatient samples, and for primary cocaine and heroin users. Similarly, CARROLL2006A found no statistically significant differences in days using primary substances.

MITCHESON2007, in a UK cluster-randomised trial, also found no statistically significant differences between the brief intervention and control groups on the primary outcome of crack cocaine use. However, the brief intervention group reported a statistically significant reduction in heroin use compared with control.

In contrast, STOTTS2001 found that an adjunctive brief intervention reduced cocaine use during cocaine detoxification. However, the intervention appeared to be more effective for those with lower motivation at baseline. This offers a possible explanation for why the effect of the brief intervention was more pronounced in this study than the others. Participants in other studies receiving formal drug treatment may have already felt motivated to change their drug use and therefore did not require an additional motivational intervention.

7.2.9 Clinical summary

The majority of meta-analyses of brief interventions do not state the context in which the intervention is conducted (for example, Burke *et al.*, 2003). The results of the current systematic review, discussed above, suggest this is important. People who misuse cannabis or stimulants, and are not in formal drug treatment, appear to respond well to brief interventions both in terms of increased abstinence levels and reduced drug use. There is some evidence to suggest people who misuse opioids who are not in formal drug treatment may also benefit from such interventions.

In contrast, for people already receiving formal drug treatment, an additional brief intervention did not appear to have much effect on abstinence or drug use in most studies. Although one study did find evidence of benefit, this was mainly accounted for by participants with lower motivation at baseline. The majority of studies were for people who misuse stimulants, although similar findings were also found for people who misuse cannabis or heroin. Ashton (2005), in a review of brief interventions, suggested that such interventions are effective for people who are ambivalent about change but ineffective for people who are motivated to change and already receiving treatment.

Results were mixed for comparisons of brief interventions with longer interventions for people who misuse cannabis or amphetamines. All the studies were for

Table 5: Study information and summary evidence table for trials of brief interventions for people who misuse drugs and are receiving drug treatment*

	Brief intervention versus standard care for people who misuse drugs and/or alcohol	Brief intervention versus standard care for people undergoing cocaine detoxification	Brief intervention versus standard care for people undergoing MMT	Brief intervention versus standard care for people who primarily misuse stimulants or heroin
Total no. of trials (total no. of participants)	1 RCT (N = 336)	1 RCT (N = 52)	1 cluster randomised trial $(N = 29)$	1 RCT (N = 208)
Study ID	CARROLL2006A	STOTTS2001	MITCHESON2007	MILLER2003
Problem drug/ diagnosis	Alcohol (50%), cannabis (20%), stimulants (24%)	Cocaine (100%)	Crack cocaine (100%)	Cocaine (53%), heroin (29%)
Baseline severity	Addiction Severity Index (ASI): Drug: 0.11 (0.12) (CARROLL2006A)	Mean duration of cocaine use: 10 years	Crack cocaine use in last 30 days: 100%	1
Treatment length	1 session	2 sessions	1 session	1 session

Length of follow-up	3 months	End of detoxification treatment (10 days)	1 month	12 months
Age (years)	33	35	39	33
Evidence profile table number (Appendix 16)	Table A16-2	Table A16-2	Table A16-2	Table A16-2
Overall quality of evidence	Low	Moderate	Moderate	Low
Abstinence	I	Abstinent from cocaine after detoxification: RR = 1.44 (1.03 to 2.01)	I	Abstinence: F (1, 55) = 1.12, p < .29
Drug use	Days of primary substance use at 1-month follow-up: SMD = -0.11 (-0.33 to 0.10) Days of primary substance use at 3-month follow-up: SMD = 0.04 (-0.18 to 0.25)	1	Days of crack-cocaine use in last 30 days: SMD = -0.07 (-0.81 to 0.67)	Illicit drug use: F (3, 157) = 0.89, p < .45

*RR > 1 favours brief intervention; negative SMD values favour brief intervention.

people seeking drug treatment. Individual relapse-prevention CBT, lasting between four and nine sessions, was associated with greater levels of abstinence and reductions in drug use for people who misuse cannabis, although interventions of such duration are effectively brief treatments. However, no differences were found for group relapse-prevention CBT for cannabis misuse or individual relapse-prevention CBT for amphetamine misuse. Further research is required to assess the efficacy of brief interventions in comparison with individual and group relapse-prevention CBT, other interventions, and with people who misuse drugs other than cannabis.

7.2.10 Health economics

Literature review of health economics evidence

OVERVIEW OF THE REVIEW

The systematic literature review for economic studies identified one study that assessed the cost effectiveness of brief interventions. The full reference for and characteristics of the study are presented in the evidence tables for economic studies in Appendix 13.

BRIEF INTERVENTIONS VERSUS STANDARD CARE

Storer (2003) conducted a cost–benefit analysis alongside a cohort study to assess the impact of brief interventions in the treatment of substance misuse disorders in the US. The study population consisted of 444 people admitted to a medical centre because of drug misuse. The study compared the readmission rates between people who received brief interventions as part of standard care, and those who did not. The difference in readmission rates was 16.8% lower in people who had received brief interventions at admission. Given that the average cost of a second admission was very high (US\$17,834) compared with the cost of a brief intervention (US\$153), this 16.8% difference represented a cost saving of US\$2,804 per person.

The above study is characterised by a number of limitations. Factors affecting reduced readmission rates in people who had received brief interventions were not specified; the perspective of the analysis was very narrow as it included only the costs of inpatient services. Nevertheless, the study demonstrated that brief interventions reduced readmission rates and associated inpatient costs.

Economic modelling

Provision of brief interventions for people who misuse drugs who are not in formal drug treatment and for those not in treatment but who are seeking treatment was identified as an area with potential resource implications. A decision-analytic Markov model was developed to assess the cost effectiveness of brief interventions versus providing a self-help booklet for cannabis or stimulant users not in formal treatment in the UK. Brief interventions involved one or two sessions with a mental health nurse for 30 minutes. The model consisted of two health states, following provision of the interventions assessed, that is, abstinent and not abstinent. The model was run in monthly cycles, with hypothetical cohorts of the study population followed up after receipt of either the brief intervention or self-help booklet. Cost-effectiveness analysis

using this model was performed separately for cannabis and stimulant users. According to the available clinical data, the time horizon for cannabis users was 4 months and for stimulant users 6 months. Drug misuse was measured by self-report in terms of frequency of using particular drugs during this period.

Costs and health benefits included in the analysis

The analysis adopted the perspective of the NHS. Health service costs in this model consisted only of the initial intervention drug users received at the start of the study. Additional healthcare costs, such as those associated with emergency department attendances and primary and secondary care, were not included, as there was no evidence that they differed significantly between the two groups within the time horizon of the analysis. Health benefits were measured using quality adjusted life years (QALYs).

Effectiveness data utilised in the model

Effectiveness data used in the model were derived from meta-analyses of RCTs that compared the effectiveness of brief interventions and self-help/information booklets in the study population. These RCTs were included in the systematic review of clinical studies undertaken for the guideline. The data reported outcomes in the form of percentages of service users who were abstinent at 3, 4, and 6 months' follow-up. Table 6 and Table 7 present the effectiveness data used in the economic analysis. Details of the clinical studies are provided in Appendix 14.

Table 6: Effectiveness data utilised in the economic model for cannabis users

Data derived fron	1 the guid	eline meta-analysis	Studies included			
A. Percentage of u	sers abstin	ent at 3-month follow-up				
Intervention	Mean	95% CI				
One-off brief intervention	16.67%	10.28% to 25.63%	McCAMBRIDGE2004			
Self-help booklet	5.43%	2.02% to 12.80%				
RR	3.07	1.18 to 7.98 (fixed-effects model)				
B. Percentage of us	B. Percentage of users abstinent at 4-month follow-up					
Intervention	Mean	95% CI				
Two sessions of brief intervention	19.21%	14.17% to 25.45%	STEPHENS2000 STEPHENS2002			
Self-help booklet	5.56%	3.04% to 9.75%				
RR	3.44	1.87 to 6.33 (fixed-effects model)				

Table 7: Effectiveness data utilised in the economic model for stimulant users

Data derived fron	n the guid	eline meta-analysis	Studies included
Percentage of users	s abstinent	at 6-month follow-up	
Intervention	Mean	95% CI	
Brief intervention	31.26%	27.72% to 35.03%	BAKER2005
Self-help booklet	24.64%	21.35% to 28.25%	BERNSTEIN2005 MARSDEN2006
RR	1.30	1.09 to 1.55 (fixed-effects model)	

People receiving either intervention were assumed to move from the state of abstinence to that of non-abstinence at follow-up and not vice versa. The monthly probability of moving from the abstinent to the non-abstinent state at follow-up was calculated using the reported abstinence rates at 4 months for cannabis users and at 6 months for stimulant users, assuming exponential fit.

Cost data

Owing to lack of patient-level cost data, deterministic costing of relevant resources was undertaken (that is, costs were analysed as point estimates). Relevant resource use for each intervention was estimated with the intention of reflecting UK clinical practice and subsequently combined with unit prices to provide the total intervention cost. Those receiving a one-off intervention had a 30-minute session with a community nurse (Band 6) at a cost of £53 per hour of contact (Curtis & Netten, 2006) and the control group was only provided with a self-help booklet at an estimated cost of £0.50.

Utility data

In order to express clinical outcomes in the form of QALYs, utility weights for health states relating to drug misuse were required. Utility weights represent the health-related quality of life associated with specific health states; they are estimated based on people's preferences and perceptions of quality of life characterising the health states under consideration.

Utility values required for the estimation of QALYs were derived from data reported in two recent NHS Health Technology Assessments, one of methadone and buprenorphine, and the other of oral naltrexone for the management of opioid-dependent drug users (Connock *et al.*, 2007; Adi *et al.*, 2007). Utility data in these assessments were obtained by a panel of members of the public, coordinated by the Peninsula Technology Assessment Group. The panel made valuations of given health states via the Value of Health Panel website using the standard gamble technique. The utility values resulting from this exercise are presented in Table 8.

Utility weights for service users not in treatment becoming drug free, essential in this model, were not provided in the above studies. Therefore, it was assumed that the difference in utilities between those in treatment who were abstinent and those in

Table 8: Utility values used in the economic analyses

treatment who were not abstinent was equal to the difference in utilities between those not in treatment who were abstinent and those not in treatment who were not abstinent. Since the study population in the analysis was cannabis or stimulant users, it was assumed that all of them were non-injectors and therefore the respective utilities were used.

Sensitivity analysis

In addition to the base-case analysis, which utilised the most accurate data available, one-way sensitivity analyses were undertaken to investigate the robustness of the results under the uncertainty characterising the model input parameters. Selected parameters were varied over a range of values and the impact of these variations on the results was explored. The following scenarios were tested:

- Change in the RRs of the percentage abstinence of service users receiving brief interventions versus a self-help booklet. The lower and upper 95% CIs of RRs calculated in the guideline meta-analyses, as shown in Table 6 and Table 7, were used.
- Changes in the cost of a self-help booklet. A 100% increase and a 50% decrease were examined.

Results

BRIEF INTERVENTIONS FOR CANNABIS USERS

BASE-CASE ANALYSIS

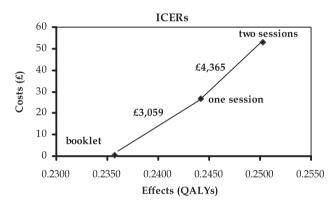
For cannabis users not in formal treatment, one-off and two-session brief interventions were compared with the provision of a self-help/information booklet, based on availability of clinical data. It is clear from Table 9 that the more intense the intervention, the more effective it is, but at increased cost.

The incremental cost-effectiveness ratio (ICER) of a two-session brief intervention versus a one-off brief intervention was £4,365 per QALY gained. The ICER of a one-off brief intervention versus the provision of the self-help booklet was £3,059 per QALY gained. Both types of brief intervention were more cost effective than the self-help booklet. The two-session intervention was more cost effective than the one-off intervention because its ICER was below the cost-effectiveness threshold of £20,000 per QALY as set by NICE (NICE, 2005b). The estimated ICERs between all options are presented in Figure 3.

Table 9: Cost and effectiveness per cannabis user for all interventions

4 months	Average total cost	Average number
Intervention	(NHS perspective)	of QALYs
Self-help booklet	£0.50	0.2357
One-off brief intervention	£26.50	0.2442
Two-session brief intervention	£53.00	0.2503

Figure 3: Incremental cost-effectiveness ratios



SENSITIVITY ANALYSIS

From an NHS perspective, brief interventions were more cost effective than provision of a self-help booklet under all scenarios explored. When the lower 95% CIs of the RRs of abstinence rates of a two-session intervention or the upper 95% CIs of the RRs of the one-off intervention versus the self-help booklet were used, then the one-off intervention became the dominant option over the two-session intervention, with ICERs versus the self-help booklet reaching £3,059 and £1,095 per QALY respectively. Results were not sensitive to a 50% decrease or 100% increase in the cost of the booklet.

BRIEF INTERVENTIONS FOR STIMULANT USERS

BASE-CASE ANALYSIS

Brief interventions for stimulant users were cost effective over 6 months. The ICER of brief interventions versus provision of a self-help booklet was £4,868 per QALY from an NHS perspective. Full results of the analysis are provided in Table 10.

SENSITIVITY ANALYSIS

From an NHS perspective, results were not sensitive to any changes in the RRs of the percentage abstinence achieved by users receiving either of the interventions. The ICER was also robust under changes in the value of the self-help/information booklet.

Full results of the one-way sensitivity analysis are provided in Table 11.

6 months Intervention	Average total cost (NHS perspective)	Average number of QALYs	ICER of brief intervention versus self-help booklet
Brief intervention	£26.50	0.3883	£4,868/QALY
Self-help booklet	£0.50	0.3829	
Difference	£26.00	0.0054	

Table 10: Results for stimulant users

Table 11: Results of sensitivity analysis

Input parameter varied	Results – NHS analysis
RRs of abstinence – Lower 95% CIs – Upper 95% CIs	£14,118/QALY £2,472/QALY
Costs of self-help/information booklet - 100% increase - 50% decrease	£4,774/QALY £4,914/QALY

Discussion

Economic analysis for brief interventions only focused on drug users not in formal drug treatment who appear to respond well. No economic analysis was performed for those users receiving formal drug treatment because brief interventions had an insignificant effect on abstinence for this group.

A limitation of the analysis is the assumption underlying the calculation of utility for those not in treatment who were abstinent. The difference between those in treatment who were abstinent and those in treatment who were not was assumed to be equal to the difference between those not in treatment who were abstinent and those not in treatment who were not, owing to lack of relevant data. Costs further to intervention costs have not been included in the analysis, but this is unlikely to have affected the results given the limited time-horizon of the analysis. On the other hand, the model assumed that abstinent and non-abstinent people incurred the same costs. This assumption conservatively biased the results against brief interventions; these were shown to significantly increase the level of abstinence compared with provision of the self-help booklet.

Despite the limitations of the analysis, the results indicate that provision of brief interventions for cannabis or stimulant users not in formal treatment is a cost-effective intervention.

7.2.11 Clinical practice recommendations

7.2.11.1 Opportunistic brief interventions focused on motivation should be offered to people in limited contact with drug services (for example, those attending

a needle and syringe exchange or primary care settings) if concerns about drug misuse are identified by the service user or staff member. These interventions should:

- normally consist of two sessions each lasting 10–45 minutes
- explore ambivalence about drug use and possible treatment, with the aim of increasing motivation to change behaviour, and provide nonjudgemental feedback.
- 7.2.11.2 Opportunistic brief interventions focused on motivation should be offered to people not in contact with drug services (for example, in primary or secondary care settings, occupational health or tertiary education) if concerns about drug misuse are identified by the person or staff member. These interventions should:
 - normally consist of two sessions each lasting 10–45 minutes
 - explore ambivalence about drug use and possible treatment, with the aim of increasing motivation to change behaviour, and provide nonjudgemental feedback.

7.3 PSYCHOSOCIAL INTERVENTIONS TO IMPROVE CONCORDANCE WITH PHYSICAL HEALTHCARE

7.3.1 Introduction

Psychosocial interventions have been developed to improve concordance with physical healthcare for problems associated with the misuse of drugs. This has the potential to improve the prevention (for example, through hepatitis B vaccinations), identification (for example, through HIV or hepatitis C tests) and treatment (for example, through anti-retrovirals for people with hepatitis C) of physical health problems in people who misuse drugs. The interventions that have received the most research attention in this area are contingency management and outreach.

Contingency management provides a system of incentives and disincentives (although almost all studies are concerned with provision of incentives) designed to make continual drug use less attractive and abstinence more attractive (Griffith *et al.*, 2000). The two major methods of providing incentives in the context of increasing concordance with physical healthcare are:

- Voucher-based reinforcement: the individual receives vouchers with various monetary values for engaging in a particular behaviour (for example, returning for a TB skin test or hepatitis B vaccination). Once earned, vouchers are exchanged for goods or services such as food or shopping.
- Cash: the individual receives cash for engaging in a particular behaviour.

Outreach involves targeting high risk and local priority groups. The four generally agreed aims of outreach work are to: identify those not already in contact with services, refer them to existing care services, initiate activities aimed at prevention and/or

reduction of drug use and at promoting safer sex and safer drug use (European Monitoring Centre for Drugs and Drug Addiction, 1999).

Current practice

There are a number of physical health problems commonly associated with drug misuse. For example, a recent report by the Health Protection Agency showed that more than two in five injecting drug users in the UK have been infected with hepatitis C. In England and Wales, hepatitis C transmission among injecting drug users is high, with one in six of those who had started to inject since the beginning of 2002 having become infected by 2004 (Health Protection Agency *et al.*, 2005).

Uptake of testing for hepatitis C among injecting drug users in contact with drug services has increased in recent years since offering tests has become part of routine management (NTA, 2006a). It is estimated, however, that around half of those injecting drug users with hepatitis C in contact with these services still remain unaware of their infection (Health Protection Agency *et al.*, 2005). It is also likely that there are substantial numbers of current and former injecting drug users who are not in contact with services who will be unaware that they have hepatitis C. A recent study found that case finding for hepatitis C in injecting drug users is cost effective (Castelnuovo *et al.*, 2006), and NICE has recommended the use of pegylated interferon and ribavirin for treatment of the disease (NICE, 2004b, 2006d).

7.3.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 12.

Table 12: Databases searched and inclusion/exclusion criteria for clinical effectiveness of interventions to improve concordance with physical healthcare

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT Observational studies
Patient population	People who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	Contingency management, outreach
Outcomes	Concordance with physical health/harm-reduction interventions

7.3.3 Studies considered⁷

For the search on psychosocial interventions to reduce injection and sexual risk behaviour (see Section 7.4), a study on increasing concordance with physical health-care was identified (MALOTTE2001). The review team then conducted an additional systematic search for RCTs and observational studies that assessed the efficacy of psychosocial interventions to increase concordance with physical healthcare.

For the efficacy review of contingency management, six RCTs (MALOTTE1998; MALOTTE1999; MALOTTE2001; ROSEN2007; SEAL2003; SORENSEN2006) met the eligibility criteria, providing data on 2,468 participants.

Two trials were for reinforcing return for a TB test (MALOTTE1998; MALOTTE1999), one trial for reinforcing concordance with prophylactic TB medication (MALOTTE2001), one for reinforcing hepatitis B vaccination (SEAL2003) and two for concordance with HIV anti-retroviral medication (ROSEN2007; SORENSEN2006).

Further information about included studies, forest plots and full evidence profiles can be found in Appendix 14, 15 and 16 respectively.

For the review of implementing contingency management, a further five studies met the eligibility criteria (Brassard *et al.*, 2004; Chaisson *et al.*, 1996; Fitzgerald *et al.*, 1999; Lorvick *et al.*, 1999; Perlman *et al.*, 2003), providing data on 2,417 participants. All studies were published in peer-reviewed journals.

Three studies were for reinforcing return for a TB skin test (Brassard *et al.*, 2004; Chaisson *et al.*, 1996; FitzGerald *et al.*, 1999), one study was for a chest x-ray to confirm TB (Perlman *et al.*, 2003), and one was for returning a TB skin test followed by prophylactic medication (Lorvick *et al.*, 1999).

7.3.4 Contingency management to improve physical healthcare

Table 13 shows that contingency management, with either cash or vouchers, is substantially more effective than standard care or outreach for increasing concordance with a range of physical healthcare interventions, including returning for TB skin tests and hepatitis B vaccinations, and concordance with medication (TB prophylaxis and HIV anti-retrovirals). The large effect sizes and the consistency of results across a range of physical health interventions drawn from large trials (totalling 2,468 participants) suggest that this is a robust finding.

Implementation studies of contingency management to engage people in harm reduction treatment

Three comparative studies with historical controls (Chaisson *et al.*, 1996; FitzGerald *et al.*, 1999; Perlman *et al.*, 2003) and two case series (Brassard *et al.*, 2004; Lorvick

⁷Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 13: Summary information and evidence table for contingency management to improve physical healthcare*

	One-off CM versus standard care for concordance with TB skin tests and hepatitis B vaccination	CM versus standard outreach for concordance with prophylactic TB medication, HIV anti-retroviral medication and hepatitis B vaccination
Total no. of trials (total no. of participants)	3 RCTs $(N = 2,183)$	4 RCTs (N = 377)
Study ID	MALOTTE1998 MALOTTE1999 SEAL2003	MALOTTE2001 ROSEN2007 SEAL2003 SORENSEN2006
Problem drug or diagnosis	Injection drug use: all Crack cocaine: MALOTTE1998, 1999	Injection drug use: all Crack cocaine: MALOTTE2001 HIV positive: ROSEN2007, SORENSEN2006
Baseline severity: mean (SD)	Drug use in past 30 days: injection only – 24%, crack only – 41%, crack and injection – 23% (MALOTTE1998) Drug use in past 90 days: injection only – 11%, crack cocaine – 77%, crack and injection – 12% (MALOTTE1999) Injection in past 30 days: heroin – 74%, methamphetamine – 16%, speedball (heroin with methamphetamine) – 51% (SEAL2003)	Injection in past 30 days: heroin – 74%, methamphetamine – 16%, speedball (heroin with methamphetamine) – 51% (SEAL2003)
Nature of incentive	One-off cash payment or voucher, US\$5 to \$20 in value	Cash or vouchers

Table 13: (Continued)

	One-off CM versus standard care for concordance with TB skin tests and hepatitis B vaccination	CM versus standard outreach for concordance with prophylactic TB medication, HIV anti-retroviral medication and hepatitis B vaccination
Treatment length	Single reward for adherence to single session	6 months
Length of follow-up	Up to 5 months	Not followed up
Age (years)	18 to 43	23 to 49
Evidence profile table number (Appendix 16)	Table A16-3	Table A16-3
Overall quality of evidence	High	High
Adherence to harm-reduction intervention	Returned for skin test or vaccination: RR 2.00 (1.48 to 2.72), $K=3$, $N=828$	Completed full course of vaccination or prophylaxis: RR 6.38 (1.00 to 40.54), $K=2$, $N=206$ Proportion HIV medication taken on time: During treatment: SMD -1.16 (-1.55 to -0.78), $K=2$, $N=122$ During follow-up: SMD -0.49 (-0.85 to -0.13), $K=1$, $N=122$

*RR > 1 favours CM, negative SMD values favour CM.

et al., 1999) have documented the implementation of contingency management to enhance concordance with TB screening and prophylaxis in a variety of settings where injection drug use is prevalent.

Using a prospective comparative design, Chaisson and colleagues (1996) analysed return rates for purified protein derivative tuberculin skin test readings among 666 HIV-infected participants (49% of whom injected drugs) in an urban HIV clinic in Baltimore, US. Participants had a purified protein derivative skin test planted and were offered over three phases of the study: no intervention (n = 272); a fast-food voucher incentive, roughly US\$4 in value, on return for a purified protein derivative reading within 3 days (n = 229); or a brief educational message from the test nurse emphasising the importance of returning for a reading, in addition to a fast-food voucher upon return (n = 158). Return rates for both voucher incentive (RR = 1.38; 95% CI, 1.11 to 1.70) and voucher incentive plus education (RR = 1.74; 95% CI, 1.42 to 2.14) groups were higher than for the control group.

Similar findings were reported by FitzGerald and colleagues (1999), who studied 1,107 service users of a community-based needle and syringe exchange service in Vancouver, Canada. In the first phase of the study, 558 participants were offered no incentives, whereas the 549 participants in the second phase were offered CA\$5 cash on return for a purified protein derivative reading. The return rate was again significantly higher for the incentive group than for the control group (RR = 1.77; 95% CI, 1.59 to 1.97). Another Canadian study, a case series (Brassard *et al.*, 2004), also reported a very high return rate (94% of 262 injecting participants) for purified protein derivative readings, where a cash incentive of CA\$10 was offered contingent on return.

In a comparative study by Perlman and colleagues (2003), 177 service users of an inner-city needle and syringe exchange service in New York with a positive purified protein derivative reading were referred off site for a confirmatory chest x-ray. Consecutive cohorts of participants were offered: either standard reimbursement for transportation (n = 119) or standard reimbursement and an additional US\$25 cash incentive on return within 7 days for the chest x-ray (n = 58). The incentive group was more likely to return for the chest x-ray than the control group (RR = 2.69; 95% CI: 2.06 to 3.52).

One case series (Lorvick *et al.*, 1999) followed 205 street-recruited injection drug users in the San Francisco Bay Area, US, from initial purified protein derivative skin test through to isoniazid (anti-TB) prophylaxis (where indicated). Cash incentives of US\$10 were offered at each point of initial contact (skin-test reading, medical evaluation and prophylaxis enrolment appointment) as well as for subsequent contact for observed medication, which was administered twice weekly over a 6-month course. Adherence was high throughout, with 87% of 205 participants returning for the purified protein derivative reading and 89% of the 27 participants requiring prophylaxis completing the full course of treatment.

In summary, non-RCTs of the implementation of contingency management in routine care provide further evidence to support the effectiveness of monetary incentives in encouraging people who misuse drugs to adhere to preventive interventions for TB. These interventions were implemented in different localities across the US as

well as in Canada with apparently consistent effectiveness, which should be noted in considering whether similar interventions may be successfully implemented in the UK. Participants in the above studies were recruited from a number of different settings with a high rate of injecting drug use, including needle and syringe exchange programmes and HIV clinics. It should also be noted that, in all the studies considered, the one-off incentives were all modest in value, ranging from US\$4–25 (approximately £2–12.50).

7.3.5 Clinical summary

The main interventions assessed in this section were contingency management for one-off practices (for example, TB skin-test readings and hepatitis B vaccinations) and concordance with physical health medication (TB prophylaxis and HIV antiretrovirals). Contingency management interventions appear to be considerably more successful than standard care or outreach in increasing the proportion of participants presenting for TB tests, vaccinations for hepatitis B and concordance with TB and HIV medications. Although TB is possibly not as prevalent among drug users in the UK in comparison with the US, it is likely that these findings can be generalised to physical health problems more common in the UK (such as hepatitis C). Although there are no UK studies assessing contingency management in this context, the findings are consistent across a number of locations in the US and Canada, and also in a variety of naturalistic studies, increasing the likelihood that these effects are generalisable to other contexts.

7.3.6 Health economics

The cost of one session of contingency management for the promotion of adherence to physical healthcare practices such as TB skin-test readings and hepatitis B vaccinations in people who misuse drugs consists of the cost of a voucher (usually around £5) and the cost of a short visit to a case worker. In order to determine the cost effectiveness of this use of contingency management, a systematic review was conducted, which identified all relevant literature on cost effectiveness and cost savings of case-finding for HIV/AIDS, hepatitis B and C, and TB among people who misuse drugs. Eight studies were considered relevant for HIV, five for hepatitis B and C, and five for TB. Evidence tables for all of these studies are provided in Appendix 13.

The prevalence of HIV/AIDS among people who misuse drugs in the UK is 1.6% compared with 0.2% in the general population (Matrix Research and Consultancy, 2006). One of the most common strategies to prevent HIV infection is counselling and testing for people at risk of HIV transmission. McCarthy and colleagues (1993) have reported that, if prevalence of unidentified infection is at least 0.5%, screening for HIV in the US falls within the accepted range of cost-effectiveness. Another US study estimated an ICER of US\$30,800 per QALY for one-time screening in populations with HIV prevalence of 1.0% (Paltiel *et al.*, 2006). At 1.6%, the prevalence of

HIV/AIDS among people who misuse drugs in the UK is substantially higher than the 0.05% and 1.0% cut-off points reported in the US studies. Therefore, inspite of these studies having been conducted in the US, it is likely that screening for HIV/AIDS in a population with a high prevalence of these conditions, such as people who misuse drugs, is a cost-effective intervention in the UK too.

The prevalence of TB in the UK is 12.9 per 100,000; no specific data on the prevalence of TB in people who misuse drugs are available. In a US study, Perlman and colleagues (2001) used a decision-analytic model to estimate the cost effectiveness of monetary incentives to promote TB screening in people who misuse drugs compared with treating active TB cases that would have occurred in the absence of the intervention. They reported that contingency management, which enhanced TB screening, was cost-saving: for 1,000 drug users offered screening, the programme would avert roughly US\$180 in TB treatment costs and would result in net savings of US\$123 (2001 prices). Snyder and colleagues (1999) estimated cost effectiveness of TB prevention in methadone maintenance clinics enhanced by the use of incentives. Over a 3-year follow-up 95% of expected TB cases were prevented, and at 10 years the programme prevented 52% of expected TB cases and 57% of expected TB-related deaths. The programme was estimated to lead to cost savings of an average of US\$3,724 per case prevented (1999 prices).

Regarding hepatitis C, prevalence among people who misuse drugs in the UK is estimated at 30.4%, compared with 0.5% in the general UK population (Matrix Research and Consultancy, 2006). A recent Health Technology Assessment (Castelnuovo *et al.*, 2006) examined the cost effectiveness of testing for hepatitis C in former injecting drug users. Prevalence in the studied target population was similar to that in active drug users. Probabilistic sensitivity analysis carried out for the population of former injecting drug users indicated that the probability of case-finding for hepatitis C being cost effective at an ICER of £20,000 per QALY was 64% and at £30,000 per QALY the probability rose to 74%.

The prevalence of hepatitis B among people who misuse drugs is estimated at 16.8%, compared with almost 0% for the general UK population (Matrix Research and Consultancy, 2006). When considering injecting drug users specifically, prevalence rises to 21%. The annual treatment costs for hepatitis B have been estimated at £7.8 million (Godfrey *et al.*, 2002). Therefore, vaccination for hepatitis B, with or without screening, produces great cost savings in adult high-risk populations (Bloom *et al.*, 1993). For populations with annual rates of disease greater than 5%, hepatitis B vaccination is clearly cost saving (Dienstag *et al.*, 1983; Mulley *et al.*, 1982); although vaccination programmes are expensive to implement, costs are reduced in the long run by reducing direct healthcare costs such as interferon-D treatment or liver transplantation (Stewart, 1997).

In conclusion, contingency management as a one-off practice for improving adherence to physical healthcare is a low-cost intervention with cost-effective, and in some cases even cost-saving, implications. A number of these studies (for example, FitzGerald *et al.*, 1999; Brassard *et al.*, 2004) have looked at the effectiveness of contingency management in improving concordance with TB screening in injecting drug users. Both reported on the impact of small financial incentives for completion

of the screening programme and FitzGerald and colleagues (1999) described increased concordance (78% versus 43% following the introduction of contingency management).

7.3.7 Clinical practice recommendation

- 7.3.7.1 For people at risk of physical health problems (including transmittable diseases) resulting from their drug misuse, material incentives (for example, shopping vouchers of up to £10 in value) should be considered to encourage harm reduction. Incentives should be offered on a one-off basis or over a limited duration, contingent on concordance with or completion of each intervention, in particular for:
 - hepatitis B/C and HIV testing
 - hepatitis B immunisation
 - tuberculosis testing.

7.4 PSYCHOSOCIAL INTERVENTIONS TO REDUCE INJECTING AND SEXUAL RISK BEHAVIOURS

7.4.1 Introduction

It is widely accepted that injecting drug users are at greater risk of developing bloodborne viruses than the general population and that many engage in injecting and sexual risk behaviours. A recent prospective cohort study of new injecting drug users in London found high levels of injecting risk behaviour (Judd et *al.*, 2005). A total of 24% reported having injected in the last 4 weeks with needles and syringes used by someone else and 53% having shared injecting paraphernalia. The baseline prevalence of antibodies to hepatitis C virus was 44% and of antibodies to HIV 4%. It would appear that injecting drug users in London have a higher incidence of hepatitis C virus than those in many cities worldwide, and an incidence of HIV comparable to that among men who have sex with men attending clinics for sexually transmitted infections in London (Judd *et al.*, 2005). Therefore, reducing the risk of blood-borne viruses among injecting drug users is an important issue in the UK. It has also been noted that people who misuse crack or cocaine have also exhibited high levels of sexual risk behaviour (for example, Malow *et al.*, 1994). Therefore, it is important not to exclude other groups of people who misuse drugs from such interventions.

One of the central public health interventions to reduce injection drug use in the UK has been through the establishment of needle and syringe exchange programmes. A number of studies have assessed the efficacy of needle and syringe exchange programmes. The results have been summarised in several recent systematic reviews (for example, Gibson *et al.*, 2001; Ksobiech, 2003; Wodak & Cooney, 2006). The main aim of these studies was to assess the efficacy of needle and syringe exchange programmes on a range of outcomes, including reducing injection risk behaviour and

HIV seroconversions. While the efficacy of needle and syringe exchange programmes *per se* is beyond the scope of this guideline, the additional psychosocial elements of these programmes are assessed below.

Current practice

One of the primary methods of reducing injection risk behaviour in the UK is through the use of needle and syringe exchange programmes. In 1998, there were 2,000 needle and syringe exchange outlets in the UK distributing over 25 million syringes annually (Hunter *et al.*, 2000).

The psychosocial components of needle and syringe exchange programmes can be divided into two main aspects: methods of distributing sterile needles, and psychosocial interventions designed specifically to reduce sexual and injection risk behaviours above and beyond providing sterile needles.

The distribution of needles can vary widely in the extent of psychosocial contact involved. Some needle and syringe exchange programmes provide sterile needles by dispensing machine and therefore potentially involve very little psychosocial contact. Conversely, other programmes distribute sterile needles through counsellors and therefore may involve more opportunities for interaction with the person who misuses drugs.

Needle and syringe exchange programmes often include additional psychosocial interventions such as education about blood-borne viruses to reduce injection and sexual risk behaviours (for example, Des Jarlais, 1996; Huo, 2006).

7.4.2 Definitions of interventions

The most common intervention designed to reduce injection and sexual risk behaviour is psychoeducation.

Psychoeducation, as described here, is a programme designed for individuals or groups of people who misuse drugs that combines education about blood-borne viruses (such as HIV or hepatitis C) with skills training to improve communication skills, assertiveness, and safe sexual and injection risk behaviour. It also provides people who misuse drugs with an opportunity to ask questions and receive relevant feedback. These interventions are typically provided over four to six sessions in a variety of settings such as methadone maintenance clinics, needle and syringe exchanges, and outreach programmes.

7.4.3 Outcomes

HIV seroconversion refers to the production of specific antibodies to antigens present in the body, resulting in a change of a serologic test from negative to positive and indicating the development of antibodies in response to infection (Macpherson, 2002).

Injection risk behaviour includes the frequency of injection drug use, sharing needles and reusing needles (Darke *et al.*, 1991).

Brief interventions and reduction of injection and sexual risk behaviours

Sexual risk behaviour refers to unsafe sexual practices, including not using condoms, either with a regular or casual partner, having multiple sexual partners and anal sex (Darke *et al.*, 1991).

7.4.4 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 14.

Table 14: Databases searched and inclusion/exclusion criteria for clinical effectiveness of interventions to reduce HIV risk behaviours

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	People who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	HIV psychoeducation, contingency management, psychosocial components of needle and syringe exchange programmes, relapse-prevention CBT, standard CBT, interpersonal therapy (IPT), behavioural couples therapy (BCT), family-based interventions
Outcomes	Reduced risk behaviours associated with HIV and other blood-borne viruses, HIV seroconversion

7.4.5 Studies considered⁸

The review team conducted a new systematic search for RCTs that assessed the efficacy of psychosocial interventions to reduce sexual and injection risk behaviour.

For the review of psychoeducation, 15 trials (AVANTS2004; BAKER1993; COLON1993; ELDRIDGE1997; EPSTEIN2003; HARRIS1998, KOTRANSKI1998;

⁸Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

MALOW1994; MARGOLIN2003; O'NEILL1996; SCHILLING1991; SIEGAL 1995; SORENSEN1994 Study 1; SORENSEN1994 Study 2; STERK2003; WECHSBERG2004) met the eligibility criteria, providing data on 4,741 participants. All trials were published in peer-reviewed journals.

For the review of standard education, five trials (BAKER1993; BAKER1994; GIBSON1999 Study 1; GIBSON1999 Study 2; TUCKER2004A) met the eligibility criteria, providing data on 735 participants. All trials were published in peer-reviewed journals.

For the review of psychosocial interventions within needle and syringe exchange programmes, one RCT (KIDORF2005) met the eligibility criteria providing data on 302 participants. This trial was published in a peer-reviewed journal.

An additional search for observational studies on psychosocial interventions within needle and syringe exchange programmes was undertaken, since only one RCT on psychosocial interventions was identified from the original search and no trials that assessed directly the efficacy of machine-dispensing needle and syringe exchange programmes in comparison with counsellor-distributed programmes.

For the review of psychosocial interventions within needle and syringe exchanges, a narrative review (Dolan *et al.*, 2003) and two descriptive studies (Jacob & Stover, 2000; Nelles *et al.*, 1998) were identified.

In addition, 18 studies were excluded from the analysis. The most common reason for exclusion was not being an RCT (further information about both included and excluded studies can be found in Appendix 14).

7.4.6 Skills-based HIV psychoeducation versus standard HIV education

A number of trials were conducted on the reduction of injection and sexual risk behaviour for people who misuse drugs. Most studies assessed drug users who inject, however the analysis was not restricted to this population (see Table 15 and Table 16 for study information and summary evidence).

7.4.7 Clinical summary

A number of RCTs have been conducted to assess the efficacy of HIV psychoeducation for reducing injection and sexual risk behaviours. From this review, it appears that psychoeducational programmes have little or no effect on injection risk behaviour and a limited and inconsistent impact on the reduction of sexual risk behaviour in people who misuse drugs. Interpretation of the research is made difficult by the lack of data on HIV seroconversion rates.

Table 15: Study information table for trials of HIV education for people who misuse drugs

	Psychoeducation versus standard HIV education	Psychoeducation versus self-help booklet	Standard education versus self-help booklet	Psychoeducation versus standard education, for at-risk subgroup
Total no. of trials (total no. of participants)	13 RCTs (N = 4,502)	4 RCTs (N = 334)	5 RCTs (N = 735)	4 RCTs $(N = 2,816)$
Study ID	AVANTS2004 BAKER1993 COLON1993 ELDRIDGE1997 EPSTEIN2003 HARRIS1998 KOTRANSK11998 MALOW1994 MARGOLIN2003 O'NEILL1996 SIEGAL1995 STERK2003	BAKER1993 SCHILLING1991 SORENSEN1994 Study 1 SORENSEN1994 Study 2	BAKER1993 BAKER1994 GIBSON1999 Study 1 GIBSON1999 Study 2 TUCKER2004A	COLON1993 KOTRANSKI1998 MALOW1994 SIEGAL1995
Problem drug or diagnosis	Injection drug use: BAKER1993 COLON1993 KOTRANSKI1998 O'NEILL1996	Injection drug use: BAKER1993 Opioids (DSM-III-R/IV dependence, MMT	Injection drug use: all Heroin: TUCKER2004A Opioids (entering detoxification):	Injection drug use: COLON1993, KOTRANSKI1998, SIEGAL1995 Cocaine (DSM-III-R/IV

	SIEGAL1995 STERK2003 Crack: WECHSBERG2004	or undergoing detoxification): SCHILLING1991, SORENSEN1994:	GIBSON1999: studies 1 & 2 HIV positive: BAKER1993 (6%)	dependence): MALOW1994 HIV positive: KOTRANSKI1998
	dependence): AVANTS2004 MALOW1994 Opioids (DSM-III-R/IV dependence or MMT): AVANTS2004 HARRIS1998 MARGOLIN2003 O'NEILL1996 Court-ordered inpatient treatment: ELDRIDGE1997 HIV positive: BAKER1993 (6%), ELDRIDGE1997 (2.9%), KOTRANSKI1998 (5%), SIEGAL1995 (1.5%)	HIV positive: BAKER1993 (6%)	TUCKER2004A (64%)	(1.5%)
Treatment length	3 to 16 sessions	2 to 6 sessions	1 session	3 to 4 sessions

Table 16: Summary evidence table for trials of HIV education for people who misuse drugs*

	Psychoeducation versus standard HIV education	Psychoeducation versus self-help booklet	Standard education versus self-help booklet	Psychoeducation versus standard education, for at-risk subgroup
Total no. of trials (total no. of participants)	13 RCTs $(N = 4,412+)$	4 RCTs (N = 334)	5 RCTs (N = 735)	4 RCTs $(N = 2.816)$
Study ID	AVANTS2004 BAKER1993 COLON1993 ELDRIDGE1997 EPSTEIN2003 HARRIS1998 KOTRANSKI1998 MALOW1994 MARGOLIN2003 O'NEILL1996 SIEGAL1995 STERK2003	BAKER1993 SCHILLING1991 SORENSEN1994 Study 1 SORENSEN1994 Study 2	BAKER 1993 BAKER 1994 GIBSON 1999 Study 1 GIBSON 1999 Study 2 TUCKER 2004A	COLON 1993 KOTRANSKI1998 MALOW 1994 SIEGAL 1995
Evidence profile table number (Appendix 16)	Table A16-4	Table A16-4	Table A16-4	Table A16-4
Overall quality of evidence	Moderate	Moderate	Moderate	Moderate

Unsafe at baseline, safer at endpoint: RR 1.09 (0.98 to 1.21), K = 3, N = 1,261	Unsafe at baseline, safer at endpoint: RR 1.56 (1.25 to 1.95), K = 3, N = 1,195
Engaging in risk behaviours: 3-month follow-up: RR 0.89 (0.53 to 1.50), K = 2, N = 296 Various measures: 1- to 3-month follow-up: SMD -0.04 (-0.29 to 0.21), K = 2, N = 243 4- to 6-month follow-up: SMD -0.17 (-0.50 to 0.16), K = 2, N = 140	Engaging in risk behaviours: 3-month follow-up: RR 0.94 (0.74 to 1.21), $K = 2$, $N = 296$ Various measures: 1- to 3-month follow-up: SMD -0.09 (-0.34 to 0.17), $K = 2$, $N = 243$ 6-month follow-up: SMD -0.06 (-0.27 to 0.39), $K = 2$, $N = 140$
Various measures: SMD -0.02 (-0.33 to 0.29), K = 3, N = 166	Engaging in risk behaviours: RR 0.58 (0.35 to 0.98), K = 1, N = 92 Various measures: SMD -0.32 (-0.57 to -0.07), K = 4, N = 240
Engaging in risk behaviours: RR 0.95 (0.73 to 1.23), K = 3, N = 841 Various measures: SMD -0.21 (-0.42 to 0.00), K = 3, N = 353	Engaging in risk behaviours: Endpoint: RR 0.91 (0.73 to 1.12), K = 5, N = 1,123 6-month follow-up: RR 0.94 (0.82 to 1.07), K = 2, N = 460 Various measures: SMD -0.30 (-0.47 to -0.13), K = 5, N = 541
Injection risk behaviours	Sexual risk behaviours

*RR > 1 favours intervention, negative SMD values favour intervention.

7.4.8 Clinical practice recommendations

- 7.4.8.1 During routine contacts and opportunistically (for example, at needle and syringe exchanges), staff should provide information and advice to all people who misuse drugs about reducing exposure to blood-borne viruses. This should include advice on reducing sexual and injection risk behaviours. Staff should consider offering testing for blood-borne viruses.
- 7.4.8.2 Group-based psychoeducational interventions that give information about reducing exposure to blood-borne viruses and/or about reducing sexual and injection risk behaviours for people who misuse drugs should not be routinely provided.

7.4.9 Psychosocial components of needle and syringe exchange programmes

Modes of distribution

There are no studies that directly compare machine-distributed needle exchanges with counsellor-distributed needle exchanges. Some brief indirect comparisons can be made, although conclusions are difficult to draw from such studies. Jacob and Stover (2000) assessed the establishment of two needle and syringe exchange programmes (one in a men's prison and another in a women's prison) in Germany over a 2-year period. Both prisons were given the option of distributing needles through slot machines or by counsellors; the men's prison opted for counsellors distributing needles, whereas the women's prison opted for slot machines. Each prison offered similar levels of psychosocial support.

Although this allows some comparisons to be made between the two modes of distribution, the study was predominantly descriptive. The general conclusions were that staff and prisoners evaluated the machine distribution needle and syringe exchange programme more positively than the counsellor distribution programme. Prisoners appeared to prefer the anonymity of machine distribution of needles.

Nelles and colleagues (1998) also described the establishment of a machinedistributed needle and syringe exchange programme in a women's prison in Switzerland. There were reported reductions in sharing of needles and injection drug use.

In addition, Dolan and colleagues (2003) reviewed a study on counsellordistributed needle and syringe exchange programmes in two Spanish prisons. Once more, there was evidence of the effectiveness of the programme, with reduced levels of blood-borne viruses.

Psychosocial interventions conducted in needle and syringe exchange programmes Assessment of the efficacy of additional psychosocial interventions within needle and syringe exchange programmes requires comparison with a minimal control or no treatment group. Only one RCT was found that compared psychosocial interventions with a control in needle and syringe exchange programmes. Kidorf and colleagues (2005) compared the use of a one-session brief intervention with standard referral and an attentional control. No statistically significant differences were found between the brief intervention group and the two control groups.

7.4.10 Clinical summary

Only one trial was found that assessed an additional psychosocial intervention compared with a standard needle and syringe exchange programme. No differences were found in terms of reduction of risk behaviour. Further research is required to assess the efficacy of additional interventions within these programmes.

Most studies evaluating needle and syringe exchange programmes failed to provide enough detail on the mode of distribution. Studies that provided these details were primarily descriptive and did not seek to compare different methods of distributing needles. At present, it is not possible to conclude whether machine or counsellor distribution of syringes or needles are associated with better outcomes.

7.4.11 Research recommendation – psychosocial interventions within needle and syringe exchange programmes

7.4.11.1 For people who inject drugs, do needle and syringe exchange programmes with a greater psychosocial content reduce injection and sexual risk behaviours and rates of seroprevalence of blood-borne virus infection more than programmes with minimal psychosocial content? Examples of greater psychosocial content include distribution of syringes and needles by staff and/or provision of psychoeducation on reducing the risk of blood-borne viruses. Examples of minimal psychosocial content include machine dispensing of syringes and needles and provision of minimal or no information on reducing blood-borne virus risk.

Why this is important

There is extensive literature assessing whether needle and syringe exchange programmes reduce injection and sexual risk behaviours and HIV seroprevalence rates. However, there is very little research that seeks to distinguish the impact of the provision of sterile needles from that of the psychosocial interventions often offered within such programmes. Psychosocial contact and interventions require substantial resources; therefore it is important to assess whether these additional elements are clinically and cost effective.

8. PSYCHOLOGICAL INTERVENTIONS

8.1 INTRODUCTION

Psychological approaches to the treatment of drug misuse have been the subject of much research and debate over the years (Wanigaratne *et al.*, 2005). Such approaches vary depending on the theoretical model underpinning them but are broadly based on the use of the interaction between therapist and service user to elicit changes in the service user's behaviour (for example, drug use), as well as other related factors including cognition and emotion. This chapter is concerned with structured psychological approaches used to help people with drug problems in their efforts to change drug-using behaviour. The approaches reviewed here contrast with those reviewed within the brief interventions chapter in that they are longer in duration and usually are part of a treatment plan within specialist services.

Over recent years, there has been an increase in the development and evaluation of psychological interventions in drug misuse treatment including: CBT, motivational approaches, contingency management treatments and family-based interventions. Psychological interventions within this field have been used either as stand-alone treatments or in combination with pharmacological interventions. In order to reflect this, the chapter has been divided into four sections: psychological interventions alone that are used without pharmacological interventions, psychological interventions used in combination with opioid agonist maintenance treatment, psychological interventions used in combination with naltrexone maintenance treatment and, finally, the application of psychological treatments within broader packages of care (for example, day care and case management). In addition, the available research on self-help approaches is also reviewed.

Psychological treatments can also be used to help people who misuse drugs address coexisting disorders such as anxiety and depression. These approaches are not covered within this review and the reader is referred to the separate NICE guidelines that address psychological interventions for specific mental health problems. Healthcare professionals should note that, although the presence of substance misuse problems may impact, for example, on the duration of a formal psychological treatment, there is no evidence supporting the view that psychological treatments for common mental disorders are ineffective for people with substance misuse disorders (see for example, Woody *et al.*, 1985). A number of NICE mental health guidelines have specifically considered the interaction between common mental health problems and drug and alcohol use. For example, the post-traumatic stress disorder (PTSD) guideline (NICE, 2005a) recommends concurrent treatment of PTSD and substance

⁹www.nice.org.uk

misuse problems, except when the substance misuse problem is severe, in which case this should be treated first. Other guidelines such as for anxiety (NICE, 2004c) or obsessive-compulsive disorder (NICE, 2006e) provide advice on assessment and the impact that drug and alcohol misuse may have on the effectiveness or duration of treatment. There is also some evidence to suggest that the active treatment of comorbid mental health problems may improve substance misuse outcomes (Charney et al., 2001; Hesse, 2004; Watkins et al., 2006). This may be particularly important for service users who have achieved abstinence, or have been stabilised on maintenance medication, but whose drug use is at risk of returning or escalating due to inadequately treated anxiety or depression. The position with regard to severe mental disorders such as schizophrenia is different and current evidence suggests that specifically designed interventions are required for this group (Bellack et al., 2006).

Clinical practice recommendation

8.1.1.1 Evidence-based psychological treatments (in particular, cognitive behavioural therapy) should be considered for the treatment of comorbid depression and anxiety disorders in line with existing NICE guidance for people who misuse cannabis or stimulants, and for those who have achieved abstinence or are stabilised on opioid maintenance treatment.

Current practice

Despite the recent increase in research on psychological treatments, current UK practice is not underpinned by a strong evidence base and there is wide variation in the uptake and implementation of psychological approaches to treatment across services. A number of factors may contribute to this situation. First, the emphasis in many community-based opioid treatment services is based on pharmacological management and supportive case coordination, with practice tending to be influenced more by the background and training of those delivering treatment within services than what research has shown to be effective. Second, a considerable amount of the evidence is extrapolated from other disorders (predominantly alcohol misuse) or other healthcare systems, for example the US or Australia, and inevitably this raises questions about the applicability of the evidence to UK drug misuse services. Third, there has been weak dissemination of the evidence base concerning psychological interventions until recently (Wanigaratne *et al.*, 2005). Fourth, the limited availability of appropriately trained therapists also contributes significantly to variable access to such services in the UK (Lovell *et al.*, 2003).

Standard care in the UK typically consists of keyworking (Knight, 2006) which, as a matter of good practice, involves the building of a therapeutic relationship with the service user and which includes:

• an initial care plan, if required, to address immediate needs (for example, providing information and advice on drug and alcohol misuse)

- harm-reduction interventions
- motivational interventions to enhance retention in treatment
- developing and agreeing the care plan with the client and implementation of the care plan with interventions relevant to each stage of the treatment journey and regular care plan reviews.

While formal psychological interventions may be delivered by a keyworker, this activity is not part of the keyworking process *per se*. The keyworker may provide a level of ongoing face-to-face therapeutic support involving the use of some psychological techniques.

Most NHS drug services in the UK tend to focus on people who misuse opioids and to be dominated by substitute prescribing. People who misuse cannabis tend not to be seen as a priority and are rarely included in service contracts, although cannabis misuse is considered a more significant problem among young people and as such interventions for these service users are more readily available. Cocaine treatment services have been developed recently but tend to lack focus and use mostly education-based approaches, for which no evidence has yet been identified.

When evaluating the outcomes of the studies described below, it is important to consider that standard care in the US, where most of the research considered in this chapter has been conducted, may involve higher levels of care and regular counselling, which surpass that usually available in the UK. The American Society of Addiction Medicine (ASAM, 2001) has defined standard outpatient treatment in the US as organised, non-residential services with designated drug misuse professionals providing regular treatment sessions totalling fewer than 9 contact hours per week. Treatment might typically consist of weekly individual and/or group counselling, which would aim to address not only the drug misuse but also wider medical, psychological and social needs. 'Treatment as usual' in recent US-based multi-site clinical trials reflects this characterisation (for example, Peirce et al., 2006; Rawson et al., 2004). Timko and colleagues (2003) surveyed all 176 Veterans Affairs substance misuse treatment programmes across the US and found that nearly all (99%) provided some form of drug or alcohol counselling or psychotherapy as part of standard outpatient care, with correspondingly high (90%) utilisation by service users.

8.2 OUTCOMES

The primary outcomes assessed were **abstinence** and **drug use**.

Both **point abstinence** and **duration of abstinence** were examined. Measures based on urinalysis were preferred but studies describing only self-report measures were not excluded.

Frequency of illicit drug use is also an important measure because, although abstinence may be a desired goal, reducing drug misuse may be a more realistic way of reducing drug-related harm. Drug misuse was usually measured by self-report, often in terms of the frequency of using particular drugs over a period of time.

8.3 PSYCHOLOGICAL INTERVENTIONS ALONE FOR THE MANAGEMENT OF DRUG MISUSE (COCAINE, CANNABIS AND OPIOIDS)

8.3.1 Introduction

This section reviews the evidence for psychological interventions alone for the treatment of drug misuse; that is, without pharmacological interventions. Most of this evidence is focused on studies of drugs for which there is, as yet, little or no evidence for effective pharmacological interventions or substitute prescribing, for example cannabis and cocaine.

While most of the literature is focused on adults over the age of 18 who misuse drugs, there also exists an evidence base around psychological interventions (in particular family and social-systems interventions) for adolescents and young people. For the purposes of this guideline, a young person is defined as an individual aged 16–18, and studies have been included for review only if they were judged to include a significant proportion of participants aged 16 or above. (In each given study, at least 50% of participants are aged 16 years or over; where such information is not provided, mean age is greater than or equal to 15.5 years.)

8.3.2 Definitions of interventions

Contingency management

Contingency management considers drug use as an example of operant behaviour that is maintained partly by the pharmacological effects of the drug in combination with other social and non-drug reinforcement provided by the drug using lifestyle (Petry, 2006). Contingency management seeks to provide alternative incentives contingent on abstinence from a particular target drug. There are four primary methods of providing incentives:

- Voucher-based reinforcement: People who misuse drugs receive vouchers with various monetary values (usually increasing in value after successive periods of abstinence) for providing biological samples (usually urine) that are negative for the tested drugs. These vouchers are withheld when the biological sample indicates recent drug use. Once earned, vouchers are exchanged for goods or services that are compatible with a drug-free lifestyle.
- Prize-based reinforcement: This is more formally referred to as the 'variable magnitude of reinforcement procedure' (Prendergast *et al.*, 2006). Participants receive draws, often from a number of slips of paper kept in a fishbowl, for providing a negative biological specimen. Provision of a specimen indicating recent drug use results in the withholding of draws. Each draw has a chance of winning a 'prize', the value of which varies. Typically, about half the draws say 'Good job!'. The other half results in the earning of a prize, which may range in value from £1 to £100 (Prendergast *et al.*, 2006).

Psychological interventions

- Clinic privileges: Participants receive clinic privileges for providing a negative biological sample. Privileges include take-home methadone doses (for example, Stitzer et al., 1992), and changes in methadone dose (for example, Stitzer et al., 1986).
- Monetary incentives: There have been a few studies, mainly on offering incentives for concordance with physical health interventions (Malotte *et al.*, 1998; Malotte *et al.*, 1999; Seal *et al.*, 2003) that have assessed the use of monetary incentives. It appears that low value (for example, £1.50/US\$3) incentives are as effective as higher value (for example, £10/US\$20) incentives.

Community reinforcement approach

In community reinforcement emphasis is placed on environmental contingencies in aspects of life such as work, recreation, family involvement, and so on, to promote a lifestyle that is more rewarding than drug misuse (Roozen *et al.*, 2004). In almost all studies, the community reinforcement approach for people who misuse drugs is conducted in combination with contingency management.

Standard cognitive behavioural therapy

Standard CBT is a discrete, time-limited, structured psychological intervention, derived from a cognitive model of drug misuse (Beck *et al.*, 1993). There is an emphasis on identifying and modifying irrational thoughts, managing negative mood and intervening after a lapse to prevent a full-blown relapse (Maude-Griffin *et al.*, 1998).

Relapse-prevention cognitive behavioural therapy

This differs from standard CBT in the emphasis on training people who misuse drugs to develop skills to identify situations or states where they are most vulnerable to drug use, to avoid high-risk situations, and to use a range of cognitive and behavioural strategies to cope effectively with these situations (Carroll & Onken, 2005).

Couples-based interventions

Couples-based interventions (including behavioural couples therapy [BCT]) involve the spouse or partner expressing active support for the person who misuses drugs in reducing drug use, including via the use of behavioural contracts. Couples are helped to improve their relationship through more effective communication skills, and encouraged to increase positive behavioural exchanges through acknowledgement of pleasing behaviours and engagement in shared recreational activities (Fals-Stewart *et al.*, 2002).

Family-based interventions

In this approach, the role of familial interactions in the maintenance and treatment of drug misuse is recognised, and family members (including parents, children and siblings) are invited to take part in treatment with the individual misusing drugs. Depending on the specific needs of each family, treatment sessions may involve work with the whole family, parts of the family and individual family members (for example, Copello *et al.*, 2005).

Social-systems interventions

Developed primarily (but not exclusively) for young people, these interventions aim to address a range of risk and protective factors for drug misuse within the service user's wider social network. Family members, partners, close friends and other significant individuals (such as teachers or probation officers) may be involved in joint treatment sessions with the service user in a range of settings (for example, Henggeler *et al.*, 1999).

Interpersonal therapy

Interpersonal therapy (IPT) is a discrete, time-limited, structured psychological intervention, originally developed for the treatment of depression, which focuses on interpersonal issues and where therapist and service user: a) work collaboratively to identify the effects of key problematic areas related to interpersonal conflicts, role transitions, grief and loss, and social skills, and their effects on current drug misuse, feelings states and/or problems; and b) seek to reduce drug misuse problems by learning to cope with or resolve interpersonal problem areas (Weissman *et al.*, 2000).

Short-term psychodynamic interventions

Short-term psychodynamic interventions are derived from a psychodynamic/psychoanalytic model in which: a) therapist and patient explore and gain insight into conflicts and how these are represented in current situations and relationships, including the therapy relationship; b) service users are given an opportunity to explore feelings and conscious and unconscious conflicts originating in the past, with the technical focus on interpreting and working through conflicts; c) therapy is non-directive and service users are not taught specific skills such as thought monitoring, re-evaluation or problem solving. Treatment typically consists of 16 to 30 sessions (Leichsenring *et al.*, 2004).

8.3.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 17.

8.3.4 Studies considered¹⁰

The review team conducted a new systematic search for RCTs that assessed the efficacy of contingency management, CBT, interpersonal therapy (IPT), behavioural couples therapy (BCT), family-based interventions and short-term psychodynamic interventions.

¹⁰Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 17: Databases searched and inclusion/exclusion criteria for clinical effectiveness of psychological interventions

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	CM, CBT, BCT, community reinforcement approach, IPT, couples-based interventions, family-based interventions, social-systems interventions, psychodynamic interventions
Outcomes	Abstinence: point abstinence, duration of abstinence Drug use: frequency of using illicit drugs over a period of time

In the review of standard CBT, two trials (CRITS-CHRISTOPH1999; MAUDE-GRIFFIN1998) met the eligibility criteria, providing data on 370 participants. Both trials were for cocaine dependence and were published in peer-reviewed journals.

In the review of relapse-prevention CBT, nine trials (BROWN2002; CARROLL1991; CARROLL1994; CARROLL1998; MONTI1997; MCKAY2004; STEPHENS1994; STEPHENS2000; STEPHENS2002) met the eligibility criteria, providing data on 1,314 participants. Of these trials, six were on cocaine dependence (BROWN2002; CARROLL1991; CARROLL1994; CARROLL1998; MONTI1997; MCKAY2004) and three were on cannabis dependence (STEPHENS1994; STEPHENS2000; STEPHENS2002). All trials were published in peer-reviewed journals.

For contingency management, 14 trials (BUDNEY2006; CARROLL2006B; HIGGINS1993; HIGGINS1994; JONES2004; KADDEN2006; PETRY2004; PETRY2005A; PETRY2005B; PETRY2006; RAWSON2006; ROLL2006; SHOPTAW2005; SHOPTAW2006) met the eligibility criteria, providing data on 1,498 participants. Of these trials, six were for cocaine dependence (HIGGINS1993; HIGGINS1994; PETRY2004; PETRY2005A; PETRY2006; RAWSON2006), one for cocaine and/or heroin dependence (PETRY2005B), three for methamphetamine dependence (ROLL2006; SHOPTAW2005; SHOPTAW2006) and three for cannabis dependence (BUDNEY2006; CARROLL2006B; KADDEN2006). All trials were published in peer-reviewed journals.

For couples-based interventions, three trials (FALS-STEWART1996; KELLEY2002; WINTERS2002) met the eligibility criteria, providing data on 123 participants. All trials were published in peer-reviewed journals and were for people who were cocaine dependent or heroin dependent (all participants in these trials underwent detoxification, if required, before receiving the intervention).

For family-based and social-systems interventions for young people, six trials (DENNIS2004 Study 1, DENNIS2004 Study 2, HENGGELER1999, LATIMER2003, LIDDLE2001, WALDRON2001) met the eligibility criteria, providing data on 708 participants. All trials were published in peer-reviewed publications.

For psychodynamic interventions, one trial (CRITS-CHRISTOPH1999) met the eligibility criteria, providing data on 247 participants. This trial was published in a peer-reviewed journal and was for cocaine dependence.

For interpersonal therapy, one trial (CARROLL1991) met the eligibility criteria, providing data on 42 participants. This trial was published in a peer-reviewed journal and was for cocaine dependence.

For cue exposure therapy, no trials met the eligibility criteria.

In addition, 37 studies were excluded from the analysis. The most common reason for exclusion was no drug-use outcomes (further information about both included and excluded studies can be found in Appendix 14). Forest plots and full evidence profiles can be found in Appendix 15 and 16 respectively.

8.3.5 Cognitive and behavioural interventions

Relapse-prevention CBT appeared to be effective for cannabis dependence, particularly compared with waitlist control. However, in one trial (Stephens *et al.*, 1994), where the therapy was compared with a support group, no significant differences were found. This may be explained by the use of group therapy in this trial; individual therapy appears to be more effective (for example, Stephens *et al.*, 2002).

Neither relapse-prevention nor standard CBT was effective for the treatment of cocaine dependence. No differences were found for abstinence and drug misuse outcomes compared with control groups (for summary study information and summary of the evidence see Table 18 and Table 19).

There is strong evidence that contingency management is associated with much longer continuous periods of abstinence for cocaine compared with control groups. People in contingency management groups were more likely to be abstinent from cocaine over 3, 6, 9 and 12 continuous weeks in both prize and voucher reinforcement studies. Only one study compared prize and voucher reinforcement, and this showed a trend favouring prizes (RR = 1.59; 95% CI: 0.94 to 2.69). Although less research has been conducted on its efficacy for methamphetamine and cannabis dependence, it also appears that during treatment contingency management is more effective than control or CBT for these groups of drug users. However, this difference was not sustained at follow-up (for study information and summary of the evidence see Table 20 and Table 21).

Table 18: Study information and summary evidence table for trials of CBT versus waitlist or standard care, for people who are cocaine or cannabis dependent

	Relapse-prevention CBT versus waitlist for cannabis dependence	Relapse-prevention CBT versus social support groups for cannabis dependence	Relapse-prevention CBT versus standard care for cocaine dependence
Total no. of trials (total no. of participants)	2 RCTs (N = 444)	1 RCT $(N = 212)$	6 RCTs $(N = 658)$
Study ID	STEPHENS2000 STEPHENS2002	STEPHENS1994	BROWN2002 CARROLL1991 CARROLL1994 CARROLL1998 MONTI1997 MCKAY2004
Problem drug or diagnosis	Cannabis dependence (DSM-IV)	Cannabis dependence (DSM-IV)	Cocaine dependence (DSM-III/III-R/IV)
Treatment length	9 individual sessions: STEPHENS2002 14 group sessions: STEPHENS2000	12 group sessions + 2 booster sessions at follow-up	8 sessions: MONTI1997; 10 sessions: BROWN2002; 12 sessions: CARROLL1991, CAROLL1994; 12 individual + 12 group sessions: MCKAY2004; 16 sessions: CARROLL1998
Length of follow-up	12 months	12 months	12 months
Age (years)	34 to 36	32	27 to 42

Evidence profile table number (Appendix 16)	Table A16-8	Table A16-7	Table A16-9
Overall quality of evidence	High	Moderate	Moderate
Point abstinence	Negative urine: 4-month follow-up: RR 4.95 (2.77 to 8.85), K = 2, N = 444	Negative urine: 3-month follow-up: RR 0.74 (0.48 to 1.14), K = 1, N = 212 12-month follow-up: RR 0.75 (0.37 to 1.51), K = 1, N = 212	Self-report: Endpoint: RR 1.13 (0.95 to 1.34), K = 4, N = 469 12-month follow-up: RR 0.96 (0.71 to 1.29), K = 1, N = 257
Duration of abstinence (days in past 3 months)		1	3-month follow-up: SMD -0.05 (-0.27 to 0.18), K = 2, N = 303 6-month follow-up: SMD -0.11 (-0.34 to 0.11), K = 2, N = 301 12-month follow-up: SMD -0.13 (-0.39 to 0.13), K = 1, N = 247
Illicit drug use	1	Days per month: 3-month follow-up: SMD -0.11 (-0.41 to 0.20); 12-month follow-up: SMD -0.02 (-0.32 to 0.29), K = 1, N = 212	Drug use in last 3 months (6-month follow-up): SMD -0.19 (-0.68 to 0.30), K = 1, N = 65

Table 19: Study information and summary evidence table for trials of CBT versus waitlist or standard care, for people who are cocaine or cannabis dependent

	Standard CBT versus standard care for cocaine dependence	Relapse-prevention CBT versus IPT for cocaine dependence
Total no. of trials (total no. of participants)	2 RCTs (N = 370)	1 RCT (N = 42)
Study ID	CRITS-CHRISTOPH1999 MAUDE-GRIFFIN1998	CARROLL1991
Problem drug or diagnosis	Cocaine dependence (DSM-III-R/IV)	Cocaine dependence (DSM-III)
Treatment length	12 sessions: MAUDE-GRIFFIN1998 39 sessions: CRITS-CHRISTOPH1999	12 sessions
Length of follow-up	6 to 9 months	3 months
Age (years)	34	27
Evidence profile table number (Appendix 16)	Table A16-9	Table A16-9
Overall quality of evidence	Moderate	Low
Point abstinence	Negative urine: Endpoint: RR 1.00 (0.78 to 1.30), K = 2, N = 370	Self-report: 3-month follow-up: RR 1.71 (0.84 to 3.48), K = 1, N = 42
Duration of abstinence	_	_
Illicit drug use	-	_

Table 20: Study information table for trials of contingency management for people who misuse drugs

	CM versus control for cocaine and/or heroin use	CM versus control for methamphetamine dependence	CM versus control for cannabis dependence	CM versus relapse-prevention CBT for stimulant dependence	CM versus relapse-prevention CBT for cannabis dependence
Total no. of trials (total no. of participants)	7 RCTs $(N = 742)$	2 RCTs (N = 222)	2 RCTs (N = 183)	2 RCTs (N = 200)	3 RCTs (N = 375)
Study ID	HIGGINS1993 HIGGINS1994 JONES2004 PETRY2005A PETRY2005B PETRY2006	ROLL2006 SHOPTAW2006	CARROLL2006B KADDEN2006	RAWSON2006 SHOPTAW2005	BUDNEY2006 CARROLL2006B KADDEN2006
Problem drug or diagnosis	Cocaine dependence (DSM-III-R/IV) Opioid dependence (DSM-IV): PETRY2005B,	Methamphetamine dependence (DSM-IV)	Cannabis dependence (DSM-IV)	Cocaine dependence (DSM-IV): RAWSON2006 (90%) Metamphetamine dependence (DSM-IV): RAWSON2006 (10%), SHOPTAW2005	Cannabis dependence (DSM-IV)

Table 20: (Continued)

	CM versus control for cocaine and/or heroin use	CM versus control for methamphetamine dependence	CM versus control for cannabis dependence	CM versus relapse-prevention CBT for stimulant dependence	CM versus relapse-prevention CBT for cannabis dependence
Nature of incentive	Vouchers (HIGGINS1993, HIGGINS1994), Prizes (PETRY2004, PETRY2005A, PETRY2005B,	Vouchers	Vouchers	Vouchers	Vouchers
Treatment length	12 weeks	12 weeks	8 weeks (CARROLL 2006B) 9 weeks (KADDEN2006)	16 weeks	8 weeks (CARROLL 2006B) 9 weeks (KADDEN2006) 14 weeks (BUDNEY2006)
Length of follow-up	3 to 12 months	3 to 6 months	6 to 12 months	12 months	12 months
Age (years)	29 to 35	30 to 32	21 to 32	36 to 37	33

Table 21: Summary evidence table for trials of contingency management for people who misuse drugs*

	CM versus control for cocaine and/or heroin use	CM versus control for methamphetamine dependence	CM versus control for cannabis dependence	CM versus relapse-prevention CBT for stimulant dependence	CM versus relapse-prevention CBT for cannabis dependence
Total no. of trials (total no. of participants)	7 RCTs (N = 833)	2 RCTs (N = 222)	2 RCTs (N = 183)	2 RCTs (N = 200)	$\frac{3 \text{ RCTs}}{(N=375)}$
Study ID	HIGGINS1993 HIGGINS1994 JONES2004 PETRY2005A PETRY2005B PETRY2006	ROLL2006 SHOPTAW2006	CARROLL2006B KADDEN2006	RAWSON2006 SHOPTAW2005	BUDNEY2006 CARROLL2006B KADDEN2006
Evidence profile table number (Appendix 16)	Table A16-11	Table A16-13	Table A16-12	Table A16-13	Table A16-12
Overall quality of evidence	High	Moderate	Moderate	Moderate	Moderate

Table 21: (Continued)

	CM versus	CM versus	CM versus	CM versus	CM versus
	control for	control for	control for	relapse-prevention	relapse-prevention
	cocaine and/or	methamphetamine	cannabis	CBT for stimulant	CBT for cannabis
	heroin use	dependence	dependence	dependence	dependence
Durations of abstinence	Continuous duration for cocaine: 3 weeks: RR 1.87 (1.45 to 2.42), K = 3, N = 528 6 weeks: RR 3.79 (1.80 to 8.01), K = 2, N = 113 9 weeks: RR 2.90 (1.98 to 4.23), K = 4, N = 568 12 weeks: RR 2.90 (1.98 to 4.23), K = 4, N = 568 Continuous duration for heroin and cocaine:	Continuous duration: RR 1.44 (0.98 to 2.12), K = 2, N = 222 Longest duration: SMD -0.22 (-0.59 to 0.15), K = 1, N = 113	Continuous duration: RR 2.03 (1.15 to 3.58), K = 2, N = 183 Longest duration: SMD -0.37 (-0.87 to 0.12), K = 1, N = 64 Abstinent for past 1-3 months: 2/3-month follow-up: RR 1.77 (0.89 to 3.53), K = 2, N = 183 5/6-month follow-up: RR 1.18 (0.67 to 2.06), K = 2, N = 183 11-month follow- up: RR 0.77 (0.29 to 2.01), K = 1,	Continuous duration: 3 weeks: RR 1.66 (1.11 to 2.47), K = 1, N = 118 Longest duration: SMD -0.79 (-1.24 to -0.34), K = 1, N = 82 Proportion of urines negative: SMD -0.66 (-1.11 to -0.22), K = 1, N = 82	Continuous duration: RR 1.88 (1.21 to 2.90), K = 3, N = 242 Longest duration: SMD -0.24 (-0.73 to 0.25), K = 1, N = 64

	Negative urine: Endpoint: RR 1.11 (0.66 to 2.69), (0.89 to 1.39), K = 1, N = 82 C-month follow-up: RR 0.98 (0.78 to 1.25), K = 1, N = 82 I2-month follow- up: RR 1.23 (0.71 to 2.11), K = 3, to 1.25), K = 1, N = 82 to 1.13), K = 1, N = 82 to 1.13), K = 1, N = 82 I1/12-month follow- up: RR 0.89 (0.71 to 1.13), K = 1, N = 82 I1/12-month follow- up: RR 1.35 (0.87 to 2.10), K = 3, N = 244 I1/12-month follow-up: RR 0.80 (0.41 to 1.59), K = 2. N = 175
	Negative urine: 3-month follow- up: RR 0.97 (0.35 to 2.71), K = 1, N = 67 6-month follow- up: RR 1.13 (0.62 to 2.07), K = 1, N = 67 to 2.07), K = 1, t
	1
12 weeks: RR 5.61 (2.31 to 13.62), K = 2 N = 173 Longest duration for cocaine: SMD -0.49 (-0.91 to -0.07) K = 1, N = 91	Cocaine: 12-month follow-up: RR 1.42 (0.98 to 2.07), K = 1, N = 190
	Point abstinence

Table 21: (Continued)

	CM versus	CM versus	CM versus	CM versus	CM versus
	control for	control for	control for	relapse-prevention	relapse-prevention
	cocaine and/or	methamphetamine	cannabis	CBT for stimulant	CBT for cannabis
	heroin use	dependence	dependence	dependence	dependence
Illicit drug use	Never abstinent: RR 0.35 (0.16 to 0.74)**, K = 3, N = 212	I	I	Days used: Endpoint: SMD 0.09 (-0.34 to 0.53), K = 1, N = 82 6-month follow-up: SMD 0.28 (-0.16 to 0.71), K = 1, N = 82 12-month follow-up: SMD -0.15 (-0.59 to 0.28), K = 1, N = 82	I

SMD negative values favour intervention; in comparisons of CM and CBT negative values favour CM. *RR > 1 favours intervention; in comparisons of CM and relapse-prevention CBT > 1 favours CM.

** RR < 1 favours intervention.

8.3.6 Psychodynamic interventions

There was a lack of trials assessing psychodynamic interventions. The one included trial did not appear to be effective in terms of abstinence and illicit drug-use outcomes in comparison with a control group (for a summary of study information and evidence see Table 22).

Table 22: Study information and summary evidence table for trials of psychodynamic interventions for people who misuse drugs*

	Psychodynamic interventions versus control	
Total no. of trials (total no. of participants)	1 RCT (N = 247)	
Study ID	CRITS-CHRISTOPH1999	
Problem drug or diagnosis	Cocaine dependence (DSM-IV)	
Treatment length	26-week active phase + 12 weeks (monthly booster session)	
Length of follow-up	18 months	
Age range	40 years	
Evidence profile table number (Appendix 16)	Table A16-10	
Overall quality of evidence	Low	
Durations of abstinence	Continuous duration: 2 months: RR 0.76 (0.55 to 1.06), K = 1, N = 247	
Illicit drug use	Relapsed at 12-month follow-up: RR 1.04 (0.80, 1.36), K = 1, N = 247	

^{*}RR > 1 favours intervention; SMD negative values favour intervention

8.3.7 Family- and couples-based interventions

Couples-based interventions were consistently associated with abstinence both at end of treatment and at 6- and 12-month follow-up for people with primary stimulant or heroin dependence. In contrast, the evidence did not suggest family-based and social-systems interventions to be effective for young people (typically around 16 years of age) predominantly misusing cannabis, whether compared with CBT or a less active psychoeducational control (for further details see Table 23 and Table 24).

Table 23: Study information table for trials of family-based interventions for people who misuse drugs

			٠	
	Couples-based interventions versus relapse-prevention CBT	Family-based and social-systems interventions versus CBT for young people	Family-based and social-systems interventions versus psychoeducation for young people	Family-based and social-systems interventions versus group therapy for young people
Total no. of trials (total no. of participants)	$\frac{3 \text{ RCTs}}{(N = 198)}$	3 RCTs (N = 458)	3 RCTs (N = 200)	2 RCTs (N = 218)
Study ID	FALS-STEWART1996 KELLEY2002 WINTERS2002	DENNIS2004 Study 1 DENNIS2004 Study 2 WALDRON2001	LATIMER2003 LIDDLE2001 WALDRON2001	HENGGELER1999 LIDDLE2001
Problem drug or diagnosis	Primary cocaine dependence (DSM-III-R): FALS-STEWART1996 (51%), KELLEY2002 (38%), WINTERS2002 (22%) Primary opioid dependence (DSM-III-R): FALS-STEWART1996 (38%), KELLEY2002 (48%), WINTERS2002 (14%)	Cannabis misuse or dependence (DSM-IV)	Substance misuse or dependence (DSM-IV): LATIMER2003 (100%), WALDRON2001 (100%) Cannabis use: LATIMER2003 (98%), LIDDLE2001 (49% cannabis with alcohol) Polydrug use: LATIMER2003 (19%), LIDDLE2001 (51%)	Substance misuse or dependence (DSM-III-R): HENGGELER1999 (100%) Cannabis use: HENGGELER1999 (68%), LIDDLE2001 (49% cannabis with alcohol) Polydrug use: HENGGELER1999 (60%) LIDDLE2001 (51%)

Treatment length	12 sessions	24 sessions (family + CBT) versus 12 sessions (CBT): WALDRON2001	16 sessions: LIDDLE2001	16 sessions: LIDDLE2001
		22 sessions (parent groups + CBT + home visits) versus 12 sessions (CBT): DENNIS2004 Study 1	24 sessions (family + CBT) versus 9 sessions (psychoeducation): WALDRON2001	
		12 sessions (multi-dimensional family therapy) versus 5 sessions (CBT): DENNIS2004 Study 2	48 sessions (family + CBT) versus 16 sessions (psychoeducation): LATIMER2003	
Length of follow-up	12 months	9 to 10 months	2 to 12 months	6 to 12 months
Age (years)	Mean 34 to 36	13 to 18, 85% aged 15 to 18	13 to 18, mean 16	12 to 18, mean 16

Table 24: Summary evidence table for trials of family-based interventions for people who misuse drugs*

	Couples-based interventions versus relapse-prevention CBT	Family-based and social-systems interventions versus CBT for young people	Family-based and social-systems interventions versus psychoeducation for young people	Family-based and social-systems interventions versus group therapy for young people
Total no. of trials (total no. of participants)	3 RCTs (N = 198)	3 RCTs $(N = 458)$	3 RCTs $(N = 200)$	$ 2 \text{ RCTs} \\ \text{(N = 218)} $
Study ID	FALS-STEWART1996 KELLEY2002 WINTERS2002	DENNIS2004 Study 1 DENNIS2004 Study 2 WALDRON2001	LATIMER2003 LIDDLE2001 WALDRON2001	HENGGELER1999 LIDDLE2001
Evidence profile table number (Appendix 16)	Table A16-17	Table A16-14	Table A16-15	Table A16-16
Overall quality of evidence	Moderate	Moderate	Moderate	Moderate
Durations of abstinence	Proportion days in past 3 months: Endpoint: SMD -0.38 (-0.66 to -0.09), K = 3, N = 198 6-month follow-up: SMD -0.52 (-0.81 to -0.24), K = 3, N = 198	1	1	Proportion negative urines: Cannabis During treatment: SMD 0.22 (-0.15 to 0.58), K = 1, N = 118 During 6-month follow-up: SMD 0.05 (-0.32 to 0.41), K = 1, N = 118

	12-month follow-up: SMD -0.34 (-0.62 to -0.06), K = 3, N = 198			Cocaine During treatment: SMD 0.00 (-0.36 to 0.36), K = 1, N = 118 During 6-month follow-up: SMD 0.12 (-0.24 to 0.48), K = 1, N = 118
Illicit drug use	I	Cannabis, self-reported days of use (change from baseline): Endpoint: SMD -0.36 (-0.87 to 0.15) 3-month follow-up: SMD -0.38 (-0.89 to 0.13), K = 1, N = 60	Cannabis, self-reported days of use (change from baseline): Endpoint: SMD -0.32 (-0.71 to 0.08), K = 2, N = 101 3-month follow-up: SMD 0.08 (-0.43 to 0.59), K = 1, N = 59	I
Clinical improvement	I	Incarcerated, hospitalised or significant substance in drug use at endpoint: RR 0.97 (0.88 r = 2, N = 158 to 1.07), K = 3, N = 458	No clinical improvement in drug use at endpoint: RR 0.76 (0.60, 0.96), K = 2, N = 158	No clinical improvement in drug use at endpoint: RR 0.76 (0.57 to 1.02), K = 1, N = 100

*RR < 1 favours family-based intervention; SMD negative values favour family-based intervention.

8.3.8 Clinical summary

Stimulant misuse

People presenting to treatment with stimulant misuse (including cocaine and amphetamines) receiving contingency management were more likely to be abstinent for longer periods of time during treatment than people in the control group. Both prize- and voucher-based reinforcement were found to be effective. Despite the strong evidence for the effectiveness of contingency management, this intervention has not been widely used in the UK. Therefore taking into account the training needs of staff and service development are important if contingency management is to be implemented in the NHS.

Psychodynamic therapy was ineffective during treatment and at follow-up in significantly reducing cocaine use. Direct comparisons of relapse-prevention CBT and contingency management for stimulant misuse demonstrated the superior effectiveness of contingency management during treatment but not at follow-up. It is unclear whether the lack of difference between contingency management and relapse-prevention CBT at follow-up is due to a delay in the benefits of CBT, being observable only at follow-up, and/or a weakening of the effects of contingency management after treatment has ended.

Cannabis misuse

CBT focused on drug misuse and relapse-prevention strategies was effective for people with cannabis-related problems when compared with no intervention (a waitlist control), but a statistically significant benefit for group relapse-prevention CBT was not seen when compared with standard case management. It appears individual therapy may be more effective than group therapy. However, economic modelling comparing CBT with waitlist control for cannabis users has suggested that CBT is not a cost-effective intervention (see section 8.3.9). It should be noted that the populations in these studies had a long-standing problem of cannabis misuse of an average of 15 years' duration.

Contingency management for cannabis misuse did not appear as effective during treatment as for cocaine misuse, although there was a trend towards favouring contingency management, which was evident at follow-up.

Opioid and stimulant misuse

Individuals with cocaine and/or opioid dependence and who are in close contact with a non-drug-misusing partner benefit from behavioural couples therapy both during treatment and at follow-up.

8.3.9 Health economics

Literature review of health economics evidence

The systematic literature review identified one economic evaluation of behavioural couples therapy (Fals-Stewart *et al.*, 1997) for people who misuse drugs. Two studies that assessed the cost effectiveness of contingency management for the treatment of people who misuse cocaine were also identified (Olmstead *et al.*, 2007; Sindelar *et al.*, 2007). Full references, characteristics and results of all studies included in the economic review are presented in the evidence tables in Appendix 13.

Cost effectiveness of behavioural couples therapy was assessed in comparison with individual-based treatment in a US study (Fals-Stewart *et al.*, 1997). Males who misused substances were randomly assigned to one of the two treatments. Behavioural couples therapy was more cost effective than individual-based treatment; for each US\$100 spent, behavioural couples therapy produced greater improvements on several indicators of treatment outcome (for example, days of abstinence and legal problems). Also, the groups differed significantly at follow-up in costs related to hospitalisation, criminal justice and total social costs, always in favour of behavioural couples therapy. Total cost savings were nearly US\$5,000 per person receiving behavioural couples therapy compared with those receiving individual treatment.

Olmstead and colleagues (2006) evaluated the cost effectiveness of a prize-based intervention (contingency management) as an addition to usual care for people who misuse cocaine. Participants randomised to the incentive condition earned the chance to draw for prizes on submitting substance-negative samples; the number of draws earned increased with continued abstinence. The time frame of the study was 12 weeks. Participants assigned to prize-based contingency management (n = 209) had significantly better outcomes than participants assigned to usual care alone (n = 206), achieved significantly longer durations of continuous stimulant and alcohol abstinence (4.3 weeks versus 2.6) and submitted significantly more stimulant-negative urine samples. Base-case results of the analysis showed that the incremental cost was US\$258 (95% CI, US \$191-401) for an additional week of abstinence, US\$146 (95% CI, US\$106-269) for an additional negative urine test and US\$398 (95% CI, US\$257-1,074) for remaining in treatment for one further week. Although the study was well conducted, the authors acknowledged a number of limitations. Given that the analysis was based on data from people who misuse stimulants and alcohol, results may not be applicable to people who misuse other substances. The duration of the study (only 12 weeks) did not allow for assessment of the long-term effect of prize-based incentives.

Sindelar and colleagues (2007) assessed the cost effectiveness of lower- versus higher-cost prize-based contingency management treatment for people who misuse cocaine. In this US study participants were randomised to one of the following 12-week treatment conditions: standard treatment with drug testing; standard treatment supplemented with relatively low expected prize pay-out contingency management; and standard treatment plus higher pay-out contingency management. Opportunities for winning prizes in the two contingency management conditions were contingent on provision of opioid-, cocaine- and alcohol-negative breath samples at each visit. Effectiveness was based on longest continuous duration of abstinence, percentage completing treatment and percentage submitting drug-free samples. The higher pay-out contingency management was considered cost effective as it produced outcomes at a lower cost per unit compared with the other two interventions.

Economic modelling for contingency management

A decision-analytic Markov model was developed to assess the cost effectiveness of contingency management versus standard care for people who misuse cocaine in the UK. Contingency management involved regular contacts with a case worker over 12 weeks, combined with reinforcement in the form of vouchers exchangeable for retail

goods and services, awarded when weekly abstinence from cocaine was achieved. Standard care consisted of less regular contacts with a case worker over the 12-week period. The time horizon of the analysis was 52 weeks. Between 12 and 52 weeks people in both arms of the model were assumed to receive standard care.

ECONOMIC MODEL STRUCTURE

The economic model consisted of two health states, abstinence and non-abstinence. The model was run in weekly cycles. People receiving either intervention were assumed to move from the state of abstinence to that of non-abstinence and not vice versa. All people in the model were assumed to remain in treatment, as no data on retention rates were available from the systematic clinical-effectiveness review.

COSTS AND HEALTH BENEFITS INCLUDED IN THE ANALYSIS

The economic analysis adopted the perspective of the NHS. Costs consisted of intervention costs only. Additional healthcare costs, incurred by deaths from cocaine use, hospital admissions owing to poisoning and intoxication, as well as inpatient stays owing to mental and behavioural disorders caused by cocaine misuse (Godfrey *et al.*, 2002) were not included in the analysis. Inclusion of such costs would most likely favour contingency management, since this has been shown to be more effective than standard care in achieving abstinence among cocaine users. The measure of health benefit used in the analysis was the QALY.

EFFECTIVENESS DATA UTILISED IN THE MODEL

Effectiveness data used in the model were derived from meta-analyses of RCTs that compared the effectiveness of contingency management and standard care for people receiving treatment for cocaine dependence.

Abstinence rates for the 12-week intervention period were taken from studies that reported percentages of service users remaining abstinent from cocaine over a number of weeks within the intervention period. Follow-up data were based on one study that reported percentages of service users who were abstinent at 12 months' follow-up. Table 25 presents the effectiveness data used in the economic analysis and the clinical studies from which these were derived. Details of the clinical studies are provided in Appendix 14.

For the 12-week intervention period the model utilised data on percentages of users remaining abstinent over a number of weeks during treatment. The percentages of users who remained abstinent over consecutive periods of weeks not reported in the trials (for example over 1 week, 2 weeks, 4 weeks, and so on), were calculated using the available data and assuming exponential fit. The weekly probability of moving from the abstinence to the non-abstinence state at follow-up (between 13 and 52 weeks) was calculated using the reported abstinence rates at 12 months (52 weeks) assuming exponential fit.

COST DATA

Owing to lack of patient-level cost data, deterministic costing of relevant resources was undertaken. Relevant resource utilisation was estimated by the GDG and was subsequently combined with unit prices to provide the total intervention cost. For each intervention, the GDG estimated the frequency and duration of contacts with case workers and the frequency of urinalysis tests (dipsticks) undertaken for the

Table 25: Data on abstinence rates utilised in the economic model

Data derived	from the g	uideline meta-analysis	Studies included
A. Percentage during trea		bstinent over 3 weeks	
Intervention	Mean	95% CI	
CM	44.36%	38.33% to 50.56%	HIGGINS1993
Standard care	23.66%	18.74% to 29.37%	PETRY2004 PETRY2005a
RR	1.87	1.45 to 2.42 (fixed-effects model)	1211120034
B. Percentage during trea		bstinent over 9 weeks	
Intervention	Mean	95% CI	
CM	30.77%	24.91% to 35.69%	HIGGINS1993
Standard care	10.64%	7.38% to 14.93%	HIGGINS1994 PETRY2004
RR	2.87	1.96 to 4.20 (fixed-effects model)	PETRY2005a
C. Percentage during trea		bstinent over 12 weeks	
Intervention	Mean	95% CI	
CM	23.08%	18.41% to 28.49%	HIGGINS1993
Standard care	5.32%	3.12% to 8.8%	HIGGINS1994 PETRY2004
RR	4.24 2.52 to 7.15 (random-effects model) PETRY2005a		
D. Percentage follow-up	of users a	bstinent at 12 months'	
Intervention	Mean	95% CI	
CM	50.4%	41.37% to 59.41%	HIGGINS1994
Standard care	35.38%	24.20% to 48.3%	
RR	1.42	0.98 to 2.07 (fixed-effects model)	

detection of cocaine. Cocaine users in the contingency management arm were assumed to receive a £3 voucher for each week they remained abstinent from cocaine during the first 6 weeks in treatment, a £5 voucher for each week of abstinence during the next 6 weeks in treatment and a £10 voucher each time they were found to be abstinent in checks performed at 26, 39 and 52 weeks.

Case-worker unit costs (assumed to be equivalent to those of community nurses paid according to Band 6) were taken from Curtis and Netten (2006), and the price of

Table 26: Resource utilisation estimates and unit costs associated with contingency management and standard care

Resource utilisation (GDG opinion)

\mathbf{CM}

Weeks 1–3: three contacts per week with a case worker, lasting 20 minutes each

Weeks 4-6: two contacts per week with a case worker, lasting 20 minutes each

Weeks 7–12: one contact per week with a case worker, lasting 20 minutes

Weeks 13–52: standard care (see below)

Plus urinalysis (dipstick):

Weeks 1-12: once a week

Weeks 13-52: once a fortnight

Plus reinforcers:

£3 voucher per week of abstinence during the first 6 weeks in treatment £5 voucher per week of abstinence during the following 6 weeks in treatment £10 voucher for abstinence in checks performed at 26, 39 and 52 weeks

Standard care

Weeks 1–12: one contact per week with a case worker, lasting 30 minutes Weeks 13–52: one contact per week with a case worker, lasting 20 minutes Plus: urinalysis (dipstick) once a fortnight

Unit costs	Source
Case worker per hour of clinic contact: £53	Curtis and Netten (2006) for cost of community nurse (Band 6); qualification costs excluded
Urinalysis (dipstick): £1.50	Personal communication with a pharmacist

urine dipsticks was ascertained by personal communication with a pharmacist. Resource utilisation estimates and unit costs associated with contingency management and standard care are presented in Table 26.

UTILITY DATA

Utility values required for the estimation of QALYs were derived from Connock and colleagues (2007) and Adi and colleagues (2007). The utility values used in the analysis are presented in Table 27.

Table 27: Utility values used in the economic analysis

Health state	Utility value (range)
In treatment: drug free	0.8673 (0.525–1)
In treatment: drug reduction (non-injectors)	0.6834 (0.325–0.980)

SENSITIVITY ANALYSIS

A sensitivity analysis was undertaken to investigate the robustness of the results under the uncertainty characterising the model input parameters. Selected parameters were varied over a range of values and the impact of these variations on the results was explored. The following scenarios were tested:

- Change in the RRs of the percentage abstinence during treatment or at follow-up of cocaine users receiving contingency management versus standard care. The 95% CIs of RRs calculated in the guideline meta-analyses, as shown in Table 25, were used. Two scenarios examined the simultaneous use of the lower 95% CIs and the upper 95% CIs of all estimated RRs, respectively.
- Changes in the total value of vouchers received by abstinent service users undergoing contingency management. A 100% increase and a 50% decrease were examined.

Results

BASE-CASE ANALYSIS

Contingency management was cost-effective over 52 weeks. The ICER of contingency management versus standard care was £11,222 per QALY from an NHS perspective. Full results of the analysis are provided in Table 28.

Table 28: Results of the economic analysis: total average costs and QALYs per user under contingency management or standard care, over 1 year of follow-up

Intervention	Average total cost (NHS)	Average number of QALYs	ICER of CM versus standard care
CM	£2,660	0.79	£11,192/QALY
Standard care	£2,372	0.77	
Difference	£288	0.02	

SENSITIVITY ANALYSIS

Results were sensitive to changes in the RRs of the percentage abstinence achieved by users receiving contingency management versus standard care. When the lower 95% CIs of all estimated RRs were used, the ICER of contingency management versus standard care became £82,631 per QALY. This result was caused by the uncertainty characterising the follow-up data. When only the RRs of abstinence rates relating to the 12-week intervention period were changed to the lower 95% CIs (and RRs of abstinence rates achieved at 52-week follow-up remained intact), then the estimated ICER was £13,093 per QALY. An additional threshold analysis was undertaken to identify the value the RR of the abstinent rate of CM versus standard care should reach in order for the ICER of CM versus standard care to remain below the NICE cost-effectiveness threshold. The results showed that the RR should equal 1.23 in order for the ICER to fall below the threshold of £20,000 per QALY. The ICER was robust when changes were made to the value of reinforcing vouchers. Full results of the one-way sensitivity analysis are provided in Table 29.

Table 29: Results of sensitivity analysis

Input parameter varied	ICER
RRs of abstinence -Lower 95% CIs -Upper 95% CIs	£82,631/QALY £5,480/QALY
Costs of vouchers -100% increase -50% decrease	£12,582/QALY £10,496/QALY

LIMITATIONS OF THE ECONOMIC ANALYSIS AND OVERALL CONCLUSIONS

The results of the analysis are subject to various limitations. In order to utilise the available efficacy data, a number of assumptions were required. Follow-up data on abstinence were available for 12 months only. Weekly abstinence rates between 12 and 52 weeks were estimated from these data. In order to construct the economic model it was assumed that once people were found not abstinent, they continued using cocaine and did not achieve abstinence thereafter. This assumption may not accurately reflect abstinence trends among users over time. Also, it was assumed that all users were retained in treatment, due to lack of evidence on drop-out rates.

Healthcare costs additional to intervention costs were not included in the analysis. These were costs incurred by deaths from cocaine use, and hospital admissions owing to poisoning and intoxication, as well as inpatient stays owing to mental and behavioural disorders caused by cocaine use (Godfrey *et al.*, 2002). Voluntary sector costs, social services costs and productivity losses were also not captured in the analysis. If all these cost elements are expected to be lower when higher rates of abstinence are achieved, contingency management is likely to be more cost effective than the findings of the analysis suggest.

Despite the limitations of the analysis, the results indicate that contingency management may be a cost-effective option for people who misuse cocaine, especially when the wider economic consequences of cocaine misuse are considered. Further research is needed to explore more accurately the cost effectiveness of contingency management for cocaine users.

Economic modelling for CBT

A decision-analytic Markov model was developed to assess the cost effectiveness of CBT when compared with no intervention (a waitlist control) for people who are cannabis users. CBT involved regular contacts with clinical psychologists; the time horizon of the analysis was 17 weeks.

ECONOMIC MODEL STRUCTURE

The economic model consisted of two health states, abstinence and non-abstinence. The model was run in weekly cycles. People receiving either intervention were assumed to move from the state of abstinence to that of non-abstinence and not vice

versa. All people in the model were assumed to remain in treatment, as no data on retention rates were available from the systematic clinical-effectiveness review.

COSTS AND BENEFITS INCLUDED IN THE ANALYSIS

The economic analysis adopted the perspective of the NHS. Only intervention costs were included in the analysis, as data on further potential healthcare costs incurred by cannabis users were not available in the literature. The measure of health benefit used in the analysis was the QALY.

EFFECTIVENESS DATA UTILISED IN THE MODEL

Effectiveness data used in the model were derived from meta-analysis of RCTs that compared the effectiveness of CBT and waitlist for people who misuse cannabis. These RCTs were included in the systematic review of clinical studies undertaken for the guideline. The studies reported outcomes in the form of percentage of service users who were abstinent at 17 weeks. Table 30 presents the effectiveness data used in the economic analysis; details of the clinical studies are provided in Appendix 14.

Data derived fr	om the guideline	meta-analysis	Studies included
A. Percentage o during treatmen	f users abstinent nt	over 17 weeks	
Intervention	Mean	95% CI	
СВТ	23.81%	18.98% to 29.4%	STEPHENS2000
Waitlist	5.13%	2.8% to 9.01%	STEPHENS2002
RR	4.48	2.50 to 8.03	

Table 30: Data on abstinence rates utilised in the economic model

COST DATA

Resource use associated with the provision of CBT was estimated by the GDG and subsequently combined with UK unit prices to provide total intervention costs. It was estimated that people who misuse cannabis receive nine CBT sessions over a 17-week period. For the first 8 weeks, CBT sessions are received on a once-weekly basis, with the last session in week 12. Psychotherapists spend on average 45 minutes per session and it was assumed that after any session a dipstick is used to detect use of cannabis.

Unit costs of psychotherapy were taken from Curtis and Netten (2006) and the price of urine dipsticks was ascertained by personal communication with a pharmacist. Given that the comparator is waitlist control, its cost is zero. Resource utilisation estimates and unit costs associated with CBT are presented in Table 31.

UTILITY DATA

Utility values required for the estimation of QALYs were derived from Connock and colleagues (2007) and Adi and colleagues (2007). However, the above studies did not provide utility weights for service users not in treatment (that is, on a waiting list) becoming drug free. It was assumed that the difference in utilities between those in

Table 31: Resource utilisation estimates and unit costs associated with CBT

Resource utilisation (GDG opinio	on)
Cognitive behavioural therapy Weeks 1–8: one session per week v Week 12: one session with a psyche Plus urinalysis (dipstick) after any	
Unit costs	Source
Clinical psychologist per hour of clinic contact: £66	Curtis & Netten (2006) for cost of clinical psychologist (band 7); qualification costs excluded
Urinalysis (dipstick): £1.50	Personal communication with a pharmacist

treatment who were abstinent and those in treatment who were not was equal to the difference in utilities between those not in treatment who were abstinent and those not in treatment who were not. The utility values that were used in the economic analysis are presented in Table 32.

Table 32: Utility values used in the economic analysis

Health state	Utility value (range)
In treatment: drug free	0.8673
In treatment: drug reduction	0.6834
Not in treatment: drug free	0.8619
Not in treatment: drug users	0.6780

SENSITIVITY ANALYSIS

A sensitivity analysis was undertaken to investigate the robustness of the results under the uncertainty characterising the model input parameters. Selected parameters were varied over a range of values and the impact of these variations on the results was explored. The following scenarios were tested in the sensitivity analysis:

- Change in the RRs of the percentage abstinence over 17 weeks of service users receiving CBT versus waitlist. The lower and upper 95% CIs of RRs calculated in the guideline meta-analysis, as shown in Table 30, were used.
- Changes in the time the clinical psychotherapist spends on CBT sessions.

Results

BASE-CASE ANALYSIS

The ICER of CBT versus waitlist control was £31,151/QALY, from an NHS perspective. This value is over the cost-effectiveness threshold of £20,000/QALY as set by

NICE (NICE, 2006a). These results indicate that CBT compared with waitlist for cannabis users is not a cost-effective intervention. Full results of the analysis are provided in Table 33.

Table 33: Results of the economic analysis over 1 year of follow-up

Intervention	Average total cost (NHS/Personal Social Services [PSS])	Average number of QALYs	ICER of CM versus waitlist
CBT	£460.50	0.254	£31,151/QALY
Waitlist	£0	0.239	
Difference	£460.50	0.015	

SENSITIVITY ANALYSIS

The ICER of CBT versus waitilist remained above £20,000/QALY under all scenarios examined. Full results of the one-way sensitivity analysis are provided in Table 34.

Table 34: Results of sensitivity analysis

Input parameter varied	Results – NHS/PSS analysis
RRs of abstinence -Lower 95% CIs -Upper 95% CIs	£56,174/QALY £20,005/QALY
Duration of session -60 minutes -30 minutes	£41,196/QALY £21,105/QALY

Limitations of the economic analysis and overall conclusions

The results of the above analysis are subject to various limitations. Because the time horizon of the model is only 17 weeks, due to the lack of follow-up data, the model assesses only the short-term effects of CBT on people who misuse cannabis; a comprehensive model should have a broader time horizon in order to assess the long-term effects of CBT.

A further limitation of the study is the analysis underlying the calculation of utility for those not in treatment who were abstinent. The difference between those in treatment who were abstinent and those in treatment who were not was assumed to be equal to the difference between those not in treatment who were abstinent and those not in treatment who were not, owing to lack of relevant data.

8.3.10 Clinical practice recommendations

- 8.3.10.1 Drug services should introduce contingency management programmes as part of the phased implementation programme led by the NTA to reduce illicit drug use, promote abstinence and/or promote engagement with services for people who primarily misuse stimulants.
- 8.3.10.2 Cognitive behavioural therapy and psychodynamic therapy focused on the treatment of drug misuse should not be offered routinely to people presenting for treatment of cannabis or stimulant misuse or those receiving opioid maintenance treatment.

8.4 PSYCHOLOGICAL INTERVENTIONS IN COMBINATION WITH OPIOID AGONIST MAINTENANCE TREATMENT

8.4.1 Introduction

The use of psychological interventions in combination with drug maintenance treatment is by far the most common application of psychological interventions in UK statutory drug treatment services. The most widely used of the drug treatments is methadone, originally pioneered by Dole and Nyswander (1965) as a treatment for heroin dependence. Less commonly prescribed is buprenorphine, which is a partial opioid agonist but an accepted maintenance treatment for opioid misuse (NICE, 2006f). The rationale for maintenance treatment is that, by using a synthetic opioid, cravings are relieved and, by switching from heroin to a controlled drug, risks and harms associated with illicit drug use can be reduced (for example, injecting behaviour and illegal activities associated with obtaining drugs) and stability can be increased. This stability may create a platform from which to continue psychological work in order to cope with the risk of relapse, deal with associated problems and eventually aim to achieve abstinence and develop a drug-free lifestyle.

As previously discussed, current practice is very varied in the UK. The most common scenario is for people on a maintenance prescription to have regular contact with a worker where practical issues are discussed and reviewed. Furthermore, it is rare in UK services to deliver psychological interventions specifically focused on attempting to reduce illicit drug use within methadone or buprenorphine maintenance treatment programmes. Most commonly, a significant proportion of people in these programmes continue to experience a range of difficulties with other substances, including illicit drugs and alcohol.

8.4.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 35.

Table 35: Databases searched and inclusion/exclusion criteria for clinical effectiveness of psychological interventions in combination with opioid agonist maintenance treatment

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who are receiving opioid agonist maintenance treatment and who misuse an additional opioid, stimulant and/or cannabis
Interventions	Pharmacological maintenance treatment: buprenorphine, methadone Psychological interventions: BCT, community reinforcement approach, CM, CBT, family-based interventions, short-term psychodynamic therapy, IPT
Outcomes	Abstinence: point abstinence, duration of abstinence Drug use: frequency of using illicit drugs over a period of time

8.4.3 Studies considered¹¹

The review team conducted a new systematic search for RCTs that assessed the efficacy and/or safety of contingency management, CBT, behavioural couples therapy, short-term psychodynamic therapy, family-based interventions and interpersonal therapy in combination with opioid agonist maintenance treatment.

For methadone maintenance treatment in combination with standard CBT, one trial (WOODY1983) met the eligibility criteria, providing data on 56 participants. This trial was published in a peer-reviewed journal.

In the review of methadone maintenance treatment in combination with relapse-prevention CBT, three trials (EPSTEIN2003; RAWSON2002; UKCBTMM2004) met the eligibility criteria, providing data on 146 participants. One trial (UKCBTMM2004) was unpublished (a full trial report was obtained from the authors) and the other two were published in peer-reviewed journals.

¹¹Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

For methadone maintenance treatment in combination with contingency management, 12 trials (CHUTUAPE2001; EPSTEIN2003; MCLELLAN1993; PEIRCE2006; PETRY2002; PETRY2005C; PRESTON2000; RAWSON2002; SCHOTTEN-FELD2005; SILVERMAN1998; SILVERMAN2004; STITZER1992) met the eligibility criteria, providing data on 1,436 participants. All trials were published in peer-reviewed journals between 1992 and 2006.

For buprenorphine maintenance treatment in combination with contingency management, four trials (DOWNEY2000; GROSS2006; KOSTEN2003; SCHOTTENFELD2005) met the eligibility criteria, providing data on 243 participants. All trials were published in peer-reviewed journals.

For couples-based interventions, one trial (FALS-STEWART2001) met the eligibility criteria, providing data on 36 participants. This trial was published in a peer-reviewed journal.

For family-based interventions, one trial (CATALANO1999) met the eligibility criteria providing data on 132 participants. This trial was published in a peer-reviewed journal.

For psychodynamic interventions, two trials (WOODY1983; WOODY1995) met the eligibility criteria, providing data on 150 participants. All trials were published in peer-reviewed journals.

For programmes for treatment dropouts, no trials met the eligibility criteria.

In addition 24 studies were excluded. The most common reason for exclusion was not providing extractable data (further information about both included and excluded studies can be found in Appendix 14). Forest plots and full evidence profiles can be found in Appendix 15 and 16 respectively.

8.4.4 Cognitive and behavioural interventions

Consistent with the evidence reviewed above of primary stimulant or heroin misuse, behavioural couples therapy and family-based interventions for people undergoing methadone maintenance treatment were associated with reductions in illicit drug use. Psychodynamic interventions did not appear to be effective for reducing illicit opioid use for people undergoing methadone maintenance treatment but there was some evidence for benefit on the secondary outcome of stimulant use and for people who had higher levels of psychiatric comorbidities (for further details see Table 36 and Table 37).

Relapse-prevention and standard CBT do not appear to be effective treatment options for people undergoing methadone maintenance treatment. The majority of trials found no benefit for either form of CBT in comparison with control groups for abstinence and reduction in illicit drug use. However, there was some evidence that standard CBT may be beneficial for a sub-sample who experienced high levels of psychiatric comorbidity.

Table 36: Study information table for trials of CBT and contingency management for people in opioid agonist maintenance treatment

	Relapse-prevention CBT versus standard care within MMT	Standard CBT versus standard care within MMT	CM versus standard care within MMT	are within MMT	CM versus standard care within buprenorphine maintenance treatment
Total no. of trials (total no. of participants)	3 RCTs (N = 146)	1 RCT (N = 78)	12 RCTs (N = 1,436)		4 RCTs (N = 243)
Study ID	EPSTEIN2003 RAWSON2002 UKCBTMM2004	WOODY 1983	CHUTUAPE2001 EPSTEIN2003 MCLELLAN1993 PEIRCE2006 PETRY2002	PRESTON2000 RAWSON2002 SCHOTTENFELD 2005 SILVERMAN1998 SILVERMAN2004 STITZER1992	DOWNEY2000 GROSS2006 KOSTEN2003 SCHOTTENFELD 2005
Problem drug or diagnosis	Opioid dependence (MMT) Cocaine dependence (DSM-III-R/IV): EPSTEIN2003, RAWSON2002	Opioid dependence (MMT)	Opioid dependence (MMT) Cocaine: SILVERMAN1998 Cocaine dependence (DSM-III-R/IV): PETRY2002, 2005C; RAWSON2002; EPSTEIN2003; SILVERMAN2004	MT) 11998 SSM-III-R/IV): AWSON2002; RMAN2004	Opioid dependence (buprenorphine maintenance treatment)

Table 36: (Continued)

	Relapse-prevention CBT versus standard care within MMT	Standard CBT versus standard care within MMT	CM versus standard care within MMT	CM versus standard care within buprenorphine maintenance treatment
Nature of incentive	N/A	N/A	Vouchers (EPSTEIN2003; PRESTON2000; RAWSON2002; SILVERMAN1998; SILVERMAN2004; SCHOTTENFELD2005) Prizes (PEIRCE2006; PETRY2002; PETRY2005C) Take home methadone (CHUTUAPE2001; MCLELLAN1993; SILVERMAN2004; STITZER1992)	Vouchers
Treatment length	12 weeks	26 weeks	8 weeks: PRESTON2000 12 weeks: PEIRCE2006; EPSTEIN2003; PETRY2002; PETRY2005C; SCHOTTENFELD2005; SILVERMAN1998 16 weeks: RAWSON2002 25 weeks: STITZER1992 26 weeks: MCLELLAN1993 34 weeks: CHUTUAPE2001 52 weeks: SILVERMAN2004	12 weeks: GROSS2006; SCHOTTENFELD 2005 24 weeks: KOSTEN2003
Length of follow-up	0 to 12 months	12 months	0 to 15 months	3 to 6 months
Age (years)	27 to 42	33	35 to 44	32 to 37

Table 37: Summary evidence table for trials of CBT and contingency management for people in opioid agonist maintenance treatment*

	Relapse-prevention CBT versus standard care within MMT	Standard CBT versus standard care within MMT	CM versus standard care within MMT	CM versus standard care within buprenorphine maintenance treatment
Total no. of trials (total no. of participants)	3 RCTs $(N = 146)$	$ 1 \text{ RCT} \\ (N = 78) $	12 RCTs (N = 1,436)	4 RCTs (N = 243)
Study ID	EPSTEIN2003 RAWSON2002 UKCBTMM2004	WOODY1983	CHUTUAPE2001 EPSTEIN2003 MCLELLAN1993 PEIRCE2006 PETRY2002 PETRY2005C PRESTON2000 RAWSON2002 SCHOTTENFELD2005 SILVERMAN1998 SILVERMAN2004 STITZER1992	DOWNEY2000 GROSS2006 KOSTEN2003 SCHOTTENFELD2005
Evidence profile table number (Appendix 16)	Table A16-20	Table A16-21	Table A16-23	Table A16-24
Overall quality of evidence	Low	Low	High	Low

Table 37: (Continued)

CM versus standard care within buprenorphine maintenance treatment	Continuous abstinence: RR 0.90 (0.59 to 1.38), K = 2 N = 123 Opioids and cocaine Longest duration: SMD 20.02 (20.27 to 0.23), K54, N5243 Opioids Longest duration: SMD 20.29 (20.64 to 0.07), K 5 2, N 5 123 Cocaine Longest duration: SMD 0.01 (20.27 to 0.28), K 5 3, N 5 203
CM versus standard care within MMT	Cocaine and opioids Continuous duration: 3 weeks: RR 2.19 (1.31 to 3.65), K = 2 N = 123 K = 6, N = 328 6 weeks: RR 3.74 (1.41 to 9.92), K = 4, N = 198 8 weeks: RR 3.87 (2.61 to 5.74), K = 7, N = 702 12 weeks: RR 2.63 (1.48 to 4.67), K = 5, N = 582 20.29 (20.64 to 16 weeks: RR 18.70 (1.13 to 16 weeks: RR 23.00 (1.43 to 20.29 (20.64 to 17
Standard CBT versus standard care within MMT	1
Relapse-prevention CBT versus standard care within MMT	Cocaine Continuous duration: 3 weeks: RR 1.50 (0.72 to 3.14), K = 1, N = 60 Heroin Proportion days abstinent: Change from baseline: SMD -0.17 (-0.74 to 0.39), K = 1, N = 49
	Durations of abstinence

Point abstinence	Cocaine 12-month follow-up: RR 2.25 (1.16 to 4.36), K = 1, N = 60	I	Negative urine for cocaine and opioids: Endpoint: RR 2.65 (1.46 to 4.79), K = 2, N = 137 6-month follow-up: RR 1.31 (1.02 to 1.68), K = 6, N = 702 12-month follow-up: RR 2.00 (1.01 to 3.95), K = 1, N = 60	1
Drug use	Primary drug Endpoint, change from baseline: SMD 0.12 (-0.28 to 0.52), K = 2, N = 146 6- to 12-month follow-up, change from baseline: SMD 0.04 (-0.29 to 0.36), K = 2, N = 146	Opioids Endpoint, change from baseline: SMD 0.07 (-0.40 to 0.54), K = 1, N = 69 Cocaine Endpoint, change from baseline: SMD -0.23 (-0.70 to 0.25), K = 1, N = 69	Never abstinent from cocaine or opioids: RR 0.63 (0.40 to 1.00), K = 4, N = 218	I

*RR > 1 favours intervention; SMD negative values favour intervention.

Psychological interventions

Consistent with the evidence above of contingency management for cocaine misuse, there is good evidence that contingency management for people undergoing methadone maintenance treatment is strongly and consistently associated with longer, continuous periods of abstinence during treatment and point abstinence at 6- and 12-month follow-up. These findings were consistent for studies using vouchers, prizes and privileges as reinforcers.

However, there is no evidence in support of contingency management for people undergoing buprenorphine maintenance treatment. It appears that contingency management is not associated with improved abstinence and illicit drug-use outcomes for this population. Possible explanations for the lack of effectiveness include some studies reinforcing abstinence from more than one drug, and the low-value reinforcement utilised in one of the studies. However, while most contingency management studies for methadone maintenance focus on reinforcing abstinence from one particular drug and often have higher-value incentives, studies using contingencies similar to those for studies of people undergoing buprenorphine maintenance have also shown much greater effectiveness for methadone maintenance.

8.4.5 Couples-based, family-based, and psychodynamic interventions

There was consistent evidence of benefit for couples-based and family-based interventions. However, the evidence for psychodynamic interventions mostly suggested limited benefit (for further details see Table 38).

8.4.6 Biological testing during contingency management

An important component of contingency management is the role of biological testing for the monitoring of drug use, to ensure that incentives are provided for genuine periods of abstinence. The two main issues addressed in this section are the methods of testing that should be used in this intervention and frequency of testing.

Method of testing

The evidence for different methods of biological testing is addressed in more detail in Chapter 6 and therefore a brief summary of the findings is sufficient here. It was argued in Chapter 6 that urinalysis and oral fluid testing are the most practical methods of testing in UK drug treatment services. Therefore these methods are the focus of this discussion of the evidence. The main issues to consider when choosing a particular method of testing are the following: sensitivity and specificity, detection time, cost and acceptability.

It is generally accepted in most reviews of biological testing that urinalysis and oral fluid analysis are viable options for drug testing, with little difference in sensitivity and specificity (for example, NACB, 2006). However, it may further be argued that data on the efficacy of urinalysis is more established in comparison with oral fluid testing (NACB, 2006; DH, 2007). An important advantage of urinalysis is that

Table 38: Study information and summary evidence table for trials of family-based interventions and psychodynamic interventions for people in methadone maintenance treatment*

	Couples-based and family-based interventions versus standard care within MMT	Psychodynamic interventions versus standard care within MMT	Psychodynamic interventions versus standard CBT within MMT
Total no. of trials (total no. of participants)	2 RCTs (N = 168)	2 RCTs (N = 150)	1 RCT (N = 56)
Study ID	CATALANO1999 FALS-STEWART2001	WOODY1983 WOODY1995	WOODY1983
Problem drug or diagnosis	Opioid dependence (MMT)	Opioid dependence (MMT)	Opioid dependence (MMT)
Treatment length	12 to 32 weeks	6 to 26 weeks	26 weeks
Length of follow-up	3 to 12 months	12 months	12 months
Age (years)	34 to 35	34 to 36	30
Evidence profile table number (Appendix 16)	Table A16-18	Table A16-22	Table A16-22
Overall quality of evidence	Moderate	Low	Low

Table 38: (Continued)

	Couples-based and family–based interventions versus standard care within MMT	Psychodynamic interventions versus standard care within MMT	Psychodynamic interventions versus standard CBT within MMT
Point abstinence	I	I	I
Illicit drug use	ASI – drug subscale Endpoint: SMD – 1.22 (-1.94 to -0.50), K = 1, N = 36 Opioids (self-reported days used): Endpoint: SMD -0.47 (-0.82 to -0.12), K = 1, N = 132 Cocaine (self-reported days used): Endpoint: SMD -0.34 (-0.68 to 0.01), K = 1, N = 132 Cannabis (self-reported days used): Endpoint: SMD -0.16 (-0.51 to 0.18), K = 1, N = 132	Illicit opioids Days used: Endpoint: SMD -0.04 (-0.37 to Endpoint: 0.30), K = 2, N = 150 Stimulants Days used: Endpoint: SMD -0.38 (-0.72 to Days used: -0.05), K = 2, N = 150 Endpoint: SMD -0.38 (-0.72 to Days used: -0.05), K = 2, N = 150 Endpoint: S	Opioids Days used: Endpoint: SMD -0.08 (-0.56 to 0.41), K = 1, N = 65 Stimulants Days used: Endpoint: SMD 0.00 (-0.49 to 0.49), K = 1, N = 56

*RR >1 favours intervention; negative SMD values favour intervention; in the comparison of psychodynamic interventions and standard CBT, negative values favour psychodynamic interventions.

detection times for drugs such as opioids and cocaine are longer (2–3 days) when compared with oral fluid testing (5–48 hours) (Verstraete, 2004). A further advantage of urinalysis, in comparison with oral fluid testing, is that it is less costly. However, an advantage of oral fluid testing is that it is generally more acceptable to service users and there is less likelihood that samples may be contaminated.

The above summary of advantages and disadvantages suggests that urinalysis and oral fluid are both viable methods of drug testing within contingency management programmes. However, while the greater acceptability of oral fluid is an important advantage, the longer detection time and lower cost associated with urinalysis suggests that this should be the preferred method in such interventions. This conclusion is largely consistent with the trials of contingency management, where almost all trials have used urinalysis as the method of testing drug use.

Frequency of testing

The detection times for drugs such as opioids and cocaine as discussed above suggest that frequently biological testing is required in order to establish that service users are given incentives based on genuine abstinence from the target drugs. The detection times indicate that oral fluid tests would be required every day and urine tests probably three times per week, at least at the beginning of a contingency management intervention. No data assessing the use of oral fluid testing during contingency management has been found and therefore only data on urinalysis can be analysed in this section.

Most of the earlier studies (for example, HIGGINS1993, HIGGINS1994) used a fixed frequency of three urinalyses per week. This regimen, strictly based on the detection times of drugs in urine, was important in establishing the efficacy of contingency management and for ensuring that abstinence rates reported in such studies could be trusted. However, later studies that sought to implement contingency management in more naturalistic drug treatment settings were aware of the burden such frequent testing provided on services. Therefore a variety of frequencies have been researched in studies of contingency management that attempt to maximise robust drug testing but also seek to ensure that such programmes can be implemented in naturalistic settings.

Table 39 summarises the number of urinalyses used in contingency management studies for participants either with methadone maintenance treatment or without it. There were no studies that compared different frequencies of urinalyses directly; however, it is possible to draw some conclusions by comparing studies using different frequencies.

In relation to methadone maintenance treatment, the majority of studies requested that participants provide three samples per week throughout the time of the intervention. This is probably due to participants having more regular contact with services (in most studies participants had to visit the clinic daily to receive methadone), which made it less difficult to obtain urinalyses frequently. Including studies with one, two and three urine samples per week did not result in significant heterogeneity ($I^2 = 26.7\%$). This suggests that the responses of the service users were generally consistent across the 12 RCTs and that using less frequent urinalyses did not significantly impact on these responses.

Table 39: Study information and number of urinalyses used for contingency management

for contingency management			
	CM for cocaine and/or opioids without MMT	MMT + CM	
Total no. of trials (total no. of participants)	5 RCTs (N = 659)	11 RCTs (N = 941)	
Study ID	HIGGINS1993 HIGGINS1994 PETRY2004 PETRY2005A PETRY2005B	CHUTUAPE2001 MCLELLAN1993 PEIRCE2006 PETRY2002 PETRY2005C PRESTON2000 RAWSON2002 SCHOTTENFELD2005 SILVERMAN1998 SILVERMAN2004 STITZER1992	
Number of urinalyses	2 per week (PETRY2005A) Tapered strategy – three per week for weeks 1 to 3, two per week for weeks 4 to 6, one per week for weeks 7 to 12 (PETRY2004; PETRY2005B) Three per week (HIGGINS1993; HIGGINS1994)	One per week (CHUTUAPE2001; MCLELLAN1993) Two per week (PEIRCE2006; PETRY2002; PETRY2005c) Three per week (PRESTON 2000; RAWSON2002; SCHOTTENFELD2005; SILVERMAN1998; SILVERMAN2004; STITZER1992)	
Type of reinforcement	Vouchers (HIGGINS1993; HIGGINS1994) Prizes (PETRY2004; PETRY2005A; PETRY2005B; PETRY2006)	Vouchers (PRESTON2000; RAWSON2002; SCHOTTENFELD2005; SILVERMAN1998; SILVERMAN2004) Prizes (PEIRCE2006; PETRY2002; PETRY2005C) Take-home methadone (CHUTUAPE2001; MCLELLAN1993; SILVERMAN2004; STITZER1992)	

In relation to studies on contingency management for cocaine and/or opioid users without methadone maintenance treatment, there was more variety in how frequently urine samples were collected. Two studies used a tapering strategy where samples were collected three times per week in weeks 1–3, two times per week in weeks 4–6 and once per week in weeks 7–12. One study collected two samples per week, and two studies collected three samples per week. The frequency of urine samples collected had very little impact on the meta-analysis; the findings from studies using the tapering strategy, samples taken two times per week and samples taken three times per week were extremely consistent ($I^2 = 0\%$).

In conclusion, where there is no clear evidence for the benefit of using a particular frequency of drug testing, there is a need to balance the drug detection time with the resource implications of collecting samples. The use of the tapering strategy discussed above for urinalysis appears to be the preferable option as it begins with three urine samples per week (as suggested by the expected drug detection time), but the frequency of testing is reduced as the service user progresses through the intervention. This approach requires a lesser burden on resources while providing frequent testing early on in the intervention when it is most needed.

8.4.7 Implementation studies of contingency management

Evidence for the efficacy of contingency management in the treatment of drug misuse has been available for over a decade (Petry *et al.*, 2001) but it has not seen widespread implementation in the NHS or even in the US, where much of the efficacy research has been conducted. In this respect contingency management is not unlike many other non-pharmacological treatments where uptake of the intervention can be limited even after the publication of guidance specifically designed to promote its uptake (Sheldon *et al.*, 2004; Grimshaw *et al.*, 2004). Despite these similarities, contingency management appears to raise particular concerns about its implementation in routine care (Petry *et al.*, 2001).

The concerns raised relate to a number of areas and include the attitudes of staff and senior managers, the particularities of the RCTs and the participants recruited to such studies, the costs associated with its implementation, the reluctance of service users to willingly participate in contingency management programmes and the cultural difference between the healthcare system of the US and other, particularly publicly funded, healthcare systems such as in the UK. All of these concerns are seen as potential barriers to effective implementation and will be discussed in light of evidence from implementation studies identified.

A number of studies (Willenbring *et al.*, 2004; McGovern *et al.*, 2004; Kellogg *et al.*, 2005; Kirby *et al.*, 2006; McQuaid *et al.*, 2007; Ritter & Cameron, 2006) have looked at staff attitudes to contingency management and have reported a generally positive attitude by the majority surveyed. Four of the studies took place in the US, with one in Australia (Ritter & Cameron, 2006) and the majority of the participants were employed in publicly funded services such as the Veterans Administration substance misuse services. A number of studies used a questionnaire, the Provider

Survey of Incentives (Kirby et al., 2006), to facilitate comparisons between services. In one such comparison, between the US and Australian services, the US showed more positive responses to contingency management, but a significant number of the Australian respondents were neutral rather than negative (Ritter & Cameron, 2006). More senior staff such as senior clinicians and programme managers tended to have more positive attitudes to contingency management, whereas other staff favoured the use of other psychosocial interventions such as CBT or motivational enhancement (McGovern et al., 2004). The specific objections raised by staff are well summarised by Kirby and colleagues (2006) and mirror findings from the other studies. They include the possibility that incentive programmes are viewed by treatment providers as being too costly and labour intensive, that they are too difficult to implement, and a poor fit with what clinicians are already doing, and that treatment providers are not adequately trained to administer contingency management. A recent report of implementing contingency management in the UK (the injectable-opioid clinic in Chelsea and Westminster Hospital) found broadly similar issues (McQuaid et al., 2007). Both staff and service users cautiously supported the incentive programme. In addition, staff perceived service users to be more stable and less likely to use illicit drugs during the intervention. However, consistent with other implementation studies, there were staff concerns about the ethical implications of using incentives in the treatment of drug misuse. McQuaid and colleagues (2007) noted the importance of discussing the theoretical basis of contingency management and its ethical implications in order to gain support from staff.

A number of studies have reported on the implementation of contingency management focusing on organisational responses and service-user outcomes. In the most comprehensive report, Kellogg and colleagues (2005) describe the introduction of contingency management into large publicly funded substance misuse services in New York. The services involved in the implementation programme included: eight methadone treatment programmes, 19 outpatient chemical dependency treatment programmes, eight inpatient detoxification units, two halfway houses, a residential programme run in partnership with a community-based provider, four hospital intervention and referral services, and an intensive case management programme. The programme sought to address the concerns commonly raised and provided important information on the necessary changes required from staff, the training and programmes required to support its implementation and the responses of service users. Unsurprisingly, key to successful implementation was the endorsement of the programme directors and the willingness of the directors and implementation team to engage with the concerns of staff. This also needed to be supported with a full educational and training programme that provided clear direction for staff, many of whom were unfamiliar with the basic principles of contingency management. A crucial element was that staff recognised contingency management as an intervention aimed at changing key behaviours and not simply rewarding people for being generally well behaved. While service-user-based quantitative outcomes in this study were positive, they were very limited and concerned only with increased participation, for example in vocational rehabilitation programmes. However, a series of interviews and discussions with staff and service users suggested that contingency management had:

increased service-user motivation for treatment; facilitated therapeutic progress; improved the attitude and morale of staff; and promoted the development of more positive relationships not only between service users and staff, but also among staff members (Kellogg *et al.*, 2005). In this study contingency management shifted from being an intervention that was viewed as being potentially problematic to integrate with other interventions to becoming the main focus of interventions with service users.

Three other studies report some service-user-based outcomes; the first, Petry and colleagues (2001), is a small case series that describes the successful use of contingency management in individuals with a range of substance misuse and psychiatric problems. The second, by Lawental and Eshkol (2006), describes the impact of the implementation of contingency management in a methadone maintenance programme in a drug treatment unit in Haifa, Israel. This study describes the outcomes for two groups before implementation of contingency management (n = 35) and after (n = 41) and reports an improvement of 36% in clean urine tests (chi sq. = 11.08, p < 0.01). No other adjustments were made to the delivery of the unit's treatment programme other than the introduction of contingency management. The third, by Shoptaw and colleagues (2006), looks at the impact of contingency management on the reduced use of methamphetamine among gay and bisexual men in specialist HIV services in San Francisco. The intention of the programme was to reduce methamphetamine use and thereby also reduce risky sexual practices in a group with a high HIV prevalence. The group studied (n = 143) had a high rate of methamphetamine use, with 42.7% reporting daily use and a further 43.4% at least weekly use; 77.6% of the sample were HIV positive, with large numbers engaging in unprotected sex (for example, 70.6% reported unprotected anal sex in the previous month). The programme reported good recruitment rates, reduced drug use comparable with results in trials with similar populations (Shoptaw et al., 2005) and acceptability to service users. However, retention rates (30% at 12 weeks) were lower than in comparable programmes for non-HIV populations, which were possibly attributed to the lower reinforcement values offered. The costs were considered by the authors to be 'modest' and the implementation programme was continued following the completion of the evaluation.

8.4.8 Clinical summary

Contingency management

For people in methadone maintenance treatment programmes who misuse drugs, contingency management leads to clinically significant reductions in illicit drug use (including both opioids and cocaine), during treatment and at follow-up. As discussed in 8.3.5 and 8.4.5 above, despite strong evidence for the effectiveness of contingency management this intervention has not yet been widely used in the UK. Therefore staff training, service redesign and phased implementation may be needed for the successful implementation of this intervention in the NHS.

In contrast, the evidence for the efficacy of contingency management for people maintained on buprenorphine was weak, with no effects comparable to those obtained with contingency management and methadone maintenance treatment. This may

Psychological interventions

reflect differences in the population in the trials or comparator groups, or possibly the impact of the differential effects of the methadone and buprenorphine on the reward system underpinning contingency management.

Family- or couples-based interventions

For individuals who have contact with a family member or carer and who are receiving methadone maintenance treatment, the addition of behavioural couples therapy can lead to reduction in the use of illicit opioids or cocaine. This is consistent with the evidence summarised in 8.3.6.

Short-term psychodynamic therapy

Short-term psychodynamic therapy did not appear to reduce illicit opioid use but in one trial there was evidence of reduced stimulant use during treatment.

Cognitive behavioural therapy

Standard and relapse-prevention CBT did not show evidence of a benefit in the methadone maintenance treatment trials on opioid use but there was very limited evidence of benefits for stimulant use. Additionally, in a direct comparison between standard CBT and psychodynamic therapy, there were no statistically significant differences between the two treatments either for opioid or stimulant use.

In summary, the use of contingency management in combination with methadone maintenance treatment, but not with buprenorphine, shows significant benefit in the reduction of illicit opioid and stimulant use. Similar results are obtained for behavioural couples interventions, albeit from a more limited evidence base. There is little evidence to support the use of short-term psychodynamic psychotherapy or standard or relapse-prevention CBT in methadone treatment programmes. A small number of studies describe some of the barriers to successful implementation of contingency management and there are limited but encouraging results from these studies suggesting that it may be possible to implement contingency management programmes outside of clinical trials and in countries other than the US.

8.4.9 Health economics

Literature review of health economics evidence

The systematic literature review identified one study that examined the cost effectiveness of varying levels of counselling during methadone maintenance treatment (Kraft *et al.*, 1997) for people who misuse opioids. Full reference, characteristics and results of this study are presented in the form of evidence tables in Appendix 13.

Kraft and colleagues (1997) examined the cost effectiveness of varying levels of supplementary support services during methadone maintenance for people who misuse opioids over a 6-month follow-up in the US. During a 24-week clinical trial three treatment groups received either methadone with minimal counselling, methadone plus moderate counselling or methadone plus enhanced counselling. At the end of the 6-month follow-up (a year after the start of treatment), abstinence rates were slightly higher for the group receiving enhanced counselling compared with the moderate counselling group. However, differences in annual cost per abstinent opioid user were

significant: US\$16,485, US\$9,804 and US\$11,818 for the low, moderate and high levels of counselling respectively. These results suggested that moderate counselling was the most cost-effective option of support for methadone-maintained opioid users.

Economic modelling

A decision-analytic Markov model was developed to assess the cost effectiveness of contingency management versus standard care for people who misuse cocaine and/or illicit opioids undergoing methadone maintenance treatment in the UK. Contingency management involved regular contact with a case worker over 12 weeks, combined with reinforcement in the form of vouchers exchangeable for retail goods and services awarded to the user when weekly abstinence from cocaine and/or opioid use was achieved. Standard care consisted of less regular contact with a case worker over the 12-week period. The time horizon of the analysis was 52 weeks, during which users received methadone maintenance treatment. Between 12 weeks and 52 weeks people in both arms of the model were assumed to receive standard care.

Economic model structure

The economic model consisted of three health states:

- in treatment and abstinent
- in treatment and not abstinent
- not in treatment and not abstinent.

The model was run in weekly cycles. According to the model structure, hypothetical cohorts of the study population received the interventions under assessment and were followed for 52 weeks. People retained in treatment were either abstinent or not abstinent. People who dropped out or were lost at follow-up were assumed to have misused drugs and to have remained non-abstinent thereafter. During the 12-week intervention period, people in treatment were able to move between the abstinent and not abstinent health states. In contrast, at follow-up, people in treatment (that is, for both arms, in standard care and receiving methadone maintenance treatment) who were found not abstinent could not move back into the abstinent state. A schematic diagram of the Markov model is presented in Figure 4.

Costs and health benefits included in the analysis

The economic analysis adopted the perspective of the NHS and PSS. Costs included intervention costs and additional healthcare costs such as those associated with attendances at emergency departments and primary and secondary care for physical health problems, as well as mental healthcare. A further non-reference case analysis was undertaken. This analysis, besides NHS/PSS costs, included criminal justice system and crime victim costs, as the economic impact of drug misuse on the criminal justice system and victims of crime was judged to be significant. The measure of health benefit used in the analysis was the QALY.

Effectiveness data utilised in the model

Effectiveness data used in the model were derived from meta-analyses of RCTs that compared the effectiveness of contingency management and standard care in people who misuse cocaine and/or opioids undergoing methadone maintenance treatment.

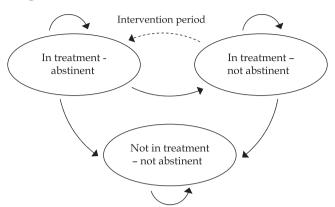


Figure 4: Schematic structure of the economic model

Abstinence rates for the 12-week intervention period were taken from studies that reported percentages of service users receiving methadone maintenance treatment remaining abstinent from cocaine and opioids over a minimum number of consecutive weeks within the intervention period. Follow-up data were based on studies that reported percentages of service users who were abstinent at a specific point in time, that is, the end of the intervention period (12 weeks) and at 6-month follow-up. Table 40 presents the effectiveness data used in the economic analysis and the clinical studies from which these were derived. Details of the clinical studies are provided in Appendix 14.

From Table 40 it can be seen that the reported percentages of users remaining abstinent over the 12 weeks of the intervention are considerably lower than the respective percentages referring to the end of the intervention period (at 12 weeks). A possible explanation of this inconsistency could lie in the heterogeneity between the two sets of studies that provided the above results (abstinence over 12 weeks and abstinence at 12 weeks respectively). However, this difference remained when data from studies reporting percentages of users both over 12 weeks and at 12 weeks were examined (in SILVERMAN1998 and SILVERMAN2004 rates of abstinence for contingency management versus standard care over 12 weeks were 8.69% and 0% respectively, and at 12 weeks 58.69% and 15.56% respectively). This discrepancy in the rates of abstinence over 12 weeks and at 12 weeks is probably explained by the fact that although some users were found abstinent at the end of the 12-week intervention period, they were not abstinent over the whole 12 weeks; that is, they had been using cocaine and/or illicit opioids in the early weeks of the intervention but achieved abstinence at the end of the intervention period. In terms of the model structure, this means that during the 12-week intervention period users could move from the non-abstinent to the abstinent state (in addition to moving from the abstinent to the non-abstinent state).

It must be noted that for the 12-week intervention period the model utilises data on percentages of users remaining abstinent over a minimum number of *consecutive* weeks; data on total weeks of abstinence were not available in the clinical studies.

Table 40: Data on abstinence rates utilised in the economic model

Data derived f	rom the gui	Studies included		
A. Percentage of users abstinent over a minimum of 1 week during treatment				
Intervention	Mean	95% CI		
CM	70.59%	58.13% to 80.70%	PETRY2002	
Standard care	48.57%	36.57% to 60.72%	PRESTON2000 SILVERMAN1998	
RR	1.47	1.10 to 1.96 (fixed-effects model)	. SILVERIVIAN 1998	
B. Percentage during treat		tinent over a minimum o	of 2 weeks	
Intervention	Mean	95% CI		
CM	61.76%	49.14% to 73.04%	PETRY2002 PRESTON2000 SILVERMAN1998	
Standard care	28.57%	18.72% to 40.80%		
RR	2.19	1.44 to 3.34 (fixed-effects model)		
C. Percentage of users abstinent over a minimum of 3 weeks during treatment				
Intervention	Mean	95% CI		
CM	49.08%	41.22% to 56.99%	PETRY2002 PRESTON2000 RAWSON2002	
Standard care	24.24%	18.07% to 31.64%		
RR	2.19	1.31 to 3.65 (random-effects model)	SCHOTTENFELD2005 SILVERMAN1998 STITZER1992	
D. Percentage of users abstinent over a minimum of 6 weeks during treatment				
Intervention	Mean	95% CI		
CM	46.59%	35.99% to 57.49%	PETRY2002	
Standard care	12.73%	7.39% to 20.76%	PRESTON2000 SCHOTTENFELD2005	
RR	4.17	2.42 to 7.18 (fixed-effects model)	SILVERMAN1998	

Continued

Table 40: (Continued)

E. Percentage of users abstinent over a minimum of 8 weeks				
during treat				
Intervention	Mean	95% CI		
CM	28.53%	23.94% to 33.59%	CHUTUAPE2001 MCLELLAN1993 PEIRCE2006	
Standard care	7.34%	4.94% to 10.70%		
RR	3.96	2.71 to 5.80 (fixed effects model)	PEIRCE2000 PETRY2002 PRESTON2000 SCHOTTENFELD2005 SILVERMAN1998	
F. Percentage of	of users abst	inent over 12 weeks dur	ing treatment	
Intervention	Mean	95% CI		
CM	12.20%	8.80% to 16.62%	MCLELLAN1993	
Standard care	4.10%	2.24% to 7.24%	PEIRCE2006 PETRY2002	
RR	3.07	1.72 to 5.48 (fixed-effects model)	SILVERMAN1998 SILVERMAN2004	
G. Percentage	of users abs	tinent at end of treatmer	t (12 weeks)	
Intervention	Mean	95% CI		
CM	40.88%	32.66% to 49.62%	EPSTEIN2003 PETRY2005C RAWSON2002	
Standard care	14.07%	8.90% to 21.35%		
RR	2.90	1.84 to 4.58 (fixed-effects model)	SILVERMAN1998	
H. Percentage of users abstinent at 6-month follow-up				
Intervention	Mean	95% CI		
CM	25.55%	18.66% to 33.84%	EPSTEIN2003	
Standard care	13.33%	8.30% to 20.51%	PETRY2005C RAWSON2002	
RR	1.88	1.15 to 3.05 (fixed-effects model)	SILVERMAN1998	

Owing to lack of such data, the economic analysis conservatively assumed that during the intervention period each user had only one period of abstinence, between 1 and 12 consecutive weeks. The percentages of users who remained abstinent over consecutive periods of weeks not reported in the trials (for example over 4 weeks, 5 weeks, 7 weeks, and so on), were calculated using the available data and assuming exponential fit.

Users in treatment at follow-up (that is, under standard care and receiving methadone maintenance treatment, for both arms of the model) were assumed to move from the state of abstinence to that of non-abstinence and not vice versa. The weekly probability of moving from the abstinent to the non-abstinent state at follow-up was calculated using the reported abstinence rates at the end of the intervention (12 weeks) and at 6 months, and assuming exponential fit. This probability was also extrapolated to the period between 6 months and 52 weeks. In order to avoid high levels of heterogeneity between 12 weeks' and 6 months' data, only data from studies that reported percentages of abstinence both at 12 weeks and at 6 months were utilised.

Although evidence suggested that there were no significant differences in retention in treatment between contingency management and standard care, rates on retention in treatment reported in the clinical trials were utilised in the economic model. Such rates were primarily available at the end of the intervention (at 12 weeks) and at the 6-month follow-up. As with abstinence rates at follow-up, only data from studies that reported rates of retention in treatment both at 12 weeks and at 6 months were utilised. From the above data, a weekly drop-out rate for the first 12 weeks and a weekly drop-out rate between 12 weeks and 6 months were calculated assuming exponential fit. The latter was also applied to the period between 6 months and 52 weeks. Data on retention in treatment used in the economic analysis and the clinical studies from which these were derived are provided in Table 41.

Table 41: Data on retention in treatment utilised in the economic model

Data derived from the guideline meta-analysis			Studies included
A. Percentage of users remaining in the study at 12 weeks			
Intervention	Mean	95% CI	
CM	85.85%	77.42% to 91.60%	EPSTEIN2003
Standard care	81.65%	72.84% to 88.17%	PETRY2002 PETRY2005C
RR	1.05	0.94 to 1.18	
B. Percentage of users remaining in the study at 6 months			
Intervention	Mean	95% CI	
CM	75.47%	65.98% to 83.08%	EPSTEIN2003
Standard care	73.39%	63.92% to 81.19%	PETRY2002 PETRY2005C
RR	1.03	0.88 to 1.20	121K12003C

Cost data

Owing to lack of patient-level cost data, deterministic costing of relevant resources was undertaken. For each intervention assessed, the GDG estimated the frequency and duration of contacts with case workers and the frequency of urinalysis tests (dipsticks) undertaken for the detection of cocaine and/or opioids. The GDG also estimated the average daily dose of methadone prescribed to the service users over the time horizon of the analysis. Estimated resource use was subsequently combined with UK unit costs to provide the total intervention costs. People in the contingency management arm were assumed to receive a £3 voucher for each week they remained abstinent from cocaine and opioids during the first 6 weeks in treatment, a £5 voucher for each week of abstinence during the next 6 weeks in treatment, and £5 vouchers each time they were found to be abstinent in checks performed at 26, 39 and 52 weeks.

Case-worker unit costs (assumed to be equivalent to those of community nurses paid according to Band 6) were taken from Curtis and Netten (2006). The price of urine dipsticks was determined by personal communication with a pharmacist. Methadone unit costs were taken from *BNF 53* (British Medical Association, 2007). Resource utilisation estimates and unit costs associated with contingency management and standard care are presented in Table 42.

Further healthcare costs, including costs associated with attendances at an emergency department, GP visits and inpatient care for physical health problems, as well as inpatient and outpatient mental healthcare, were based on resource use data derived from the NTORS study (Gossop *et al.*, 1998). Using these data, Godfrey and colleagues (2002) estimated the annual healthcare costs incurred by people who misuse Class A drugs in England and Wales, excluding treatment for dependence. Costs were reported separately for people who misuse drugs not in treatment for dependence, for those in treatment for less than a year, and for those in treatment for more than a year. Costs relating to the first two categories of people who misuse drugs were utilised in the economic analysis. Table 43 provides healthcare resource use estimates and respective costs incurred by people who misuse drugs in England and Wales, as reported by Godfrey and colleagues (2002).

From Table 43 it can be seen that healthcare costs are higher for people who misuse drugs in treatment than for those not in treatment. This finding suggests that increasing the number of those in treatment may result in an increase in healthcare costs in the short run. In addition, healthcare costs estimated by Godfrey and colleagues (2002) were not adjusted to take into account the impact of current drug misuse on future healthcare demands. As a consequence, potential future costs from infectious disease risks among people who misuse drugs have not been included in the above estimates of healthcare costs and, consequently, in the economic analysis undertaken for this guideline.

Godfrey and colleagues (2002) did not report data on PSS costs associated with drug misuse; for this reason, such costs have been assumed to be negligible in the economic analysis. Criminal justice system and crime victim costs, which were included in the non-reference case analysis, were available in Godfrey and colleagues (2002). Criminal justice system costs included costs associated with drug arrests, arrests for acquisitive crimes, stays in police custody, appearances in court and stays

Table 42: Resource utilisation estimates and unit costs associated with contingency management and standard care

Resource utilisation (GDG opinion)

\mathbf{CM}

Weeks 1–3: three contacts per week with a case worker, lasting 30 minutes each

Weeks 4-6: two contacts per week with a case worker, lasting 30 minutes each

Weeks 7–12: one contact per week with a case worker, lasting 30 minutes

Weeks 13–52: standard care (see below)

Plus urinalysis (dipstick) Weeks 1–12: once per week Weeks 13–52: once in a fortnight

Plus reinforcers:

£3 voucher per week of abstinence during the first 6 weeks in treatment

£5 voucher per week of abstinence during the following 6 weeks in treatment

£5 voucher for abstinence in checks performed at 26, 39 and 52 weeks

Standard care

Weeks 1–52: one contact per week with a case worker, lasting 20 minutes

Plus: urinalysis (dipstick) once in a fortnight

Methadone

30 mg daily between 1–3 weeks 60 mg daily between 4–6 weeks 90 mg daily between 7–52 weeks

Unit costs	Source
Case worker per hour of clinic contact: £53	Curtis & Netten (2006); cost of community nurse (Band 6); qualification costs excluded
Urinalysis (dipstick): £1.50	Personal communication with a pharmacist
Methadone oral solution 1 mg/ml: £0.0135/mg	BNF 53 (British Medical Association, 2007)

Table 43: Annual healthcare resource use and costs incurred by people who misuse Class A drugs in England and Wales*

A. People who misuse drugs not in treatment			
Type of healthcare	Annual resource use per user	Annual cost per user	
Primary care	3.6 GP visits	£65	
Emergency departments	0.7 episodes	£197	
Inpatient care	1.75 days	£390	
Community mental health	1.3 visits	£65	
Inpatient mental health	1.5 days	£216	
TOTAL		£933 (£780 to 1,400)	
B. People who use drugs in treatment for less than a year			
Type of healthcare	Annual resource use per user	Annual cost per user	
Primary care	5.6 GP visits	£101	
Emergency departments	0.8 episodes	£226	
Inpatient care	2.8 days	£624	
Community mental health	0.8 visits	£40	
Inpatient mental health	0.4 days	£58	
TOTAL		£1,049 (£873 to £1,572)	

^{*2000} prices; costs in brackets refer to lowest and highest estimates.

in prison. Crime victim costs referred to material or physical damage, crime victims' loss, and expenditure in anticipation of crime. Table 44 provides estimates of crime-related costs for people who misuse drugs not in treatment and for those in treatment for less than a year, as reported in Godfrey and colleagues (2002).

It should be emphasised that the amount of healthcare costs and crime-related costs incurred by people who misuse drugs as reported in Godfrey and colleagues (2002) exclusively depended on whether people were engaged in treatment or not; the impact of effectiveness of treatment (in terms of achieving abstinence from drug misuse) on these costs was not discussed in the study. Therefore, the present economic analysis has not differentiated between abstinent users and non-abstinent users in treatment for estimation of costs.

Healthcare costs were adjusted to 2006 prices using the hospital and community health services pay and prices inflation rates (Curtis & Netten, 2005). The inflation rate for 2005/6 was estimated using the average value of the hospital and community

Table 44: Annual criminal justice system and crime victim costs incurred by people who misuse Class A drugs in England and Wales*

A. People who misuse drugs not in treatment		
Criminal justice system cost	£7,037 (£5,864 to £10,556)	
Victim costs of crime	£30,827 (£25,691 to £46,242)	
TOTAL £37,864 (£31,555 to £56,798)		
B. Drug users in treatment for less than a year		
Criminal justice system cost	£8,397 (£6,997 to £12,582)	
Victim costs of crime	£8,893 (£7,417 to £13,357)	
TOTAL	£17,290 (£14,414 to £25,939)	

^{*2000} prices; costs in brackets refer to lowest and highest estimates.

health services pay and prices inflation rates of the previous 3 years. Crime-related costs were adjusted to 2006 prices using the Retail Prices Index (Office for National Statistics, 2007).

Utility data

Utility values required for the estimation of QALYs were derived from Connock and colleagues (2007) and Adi and colleagues (2007). The utility values in the economic analysis are presented in Table 45.

The final utility values for the health states 'in treatment – reduction in drug use' and 'not in treatment – drug misuse' were weighed according to the proportion of injectors in the population of people who misuse drugs receiving methadone maintenance treatment, reported in the NTORS study (Gossop *et al.*, 2003). According to the study, the proportion of injectors in this population was 61% at initiation of treatment and 44% at 1 year of treatment. The economic model assumed that the proportion of injectors among people who misuse drugs who dropped out of methadone maintenance

Table 45: Utility values used in the economic analysis of contingency management versus standard care for people misusing drugs receiving methadone maintenance treatment

Health state	Utility value (range)
In treatment – drug free	0.8673 (0.525 to 1)
In treatment – reduction in drug use	Injectors: 0.6332 (0.275 to 0.935) Non-injectors: 0.6834 (0.325 to 0.980)
Not in treatment – drug misuse	Injectors: 0.5880 (0.125 to 0.960) Non-injectors: 0.6780 (0.275 to 0.980)

Psychological interventions

treatment was the same as that characterising the population at initiation of treatment in Gossop and colleagues (2003).

Sensitivity analysis

A sensitivity analysis was undertaken to investigate the robustness of the results under the uncertainty characterising the model input parameters. Selected parameters were varied over a range of values and the impact of these variations on the results was explored. The following scenarios were tested in the sensitivity analysis:

- Change in RRs of the percentage abstinence over a consecutive number of weeks during treatment or at follow-up, of service users receiving contingency management versus standard care. The 95% CIs of RRs calculated in the guideline meta-analyses, as shown in Table 40, were used. Two scenarios examined the simultaneous use of the lower 95% CIs and the upper 95% CIs of all estimated RRs, respectively.
- Changes in the total value of vouchers received by abstinent service users undergoing contingency management. A 100% increase and a 50% decrease were examined.
- Changes in the additional (that is, besides intervention costs) healthcare and crime-related costs. Lowest and highest estimates reported in Godfrey and colleagues (2002), as shown in Table 43 and Table 44, were used.
- Exclusion of additional healthcare and crime-related costs, since these depended only on retention in treatment, which was not significantly different between the two strategies.
- Exclusion of crime victim costs from the non-reference case analysis, as crime victim costs differed greatly between people who misuse drugs in treatment (£8,893) and those not in treatment (£30,827) in Godfrey and colleagues (2002).

Results

BASE-CASE ANALYSIS

Contingency management was cost effective over 52 weeks. The ICER of contingency management versus standard care was £15,219 per QALY from an NHS/PPS

Table 46: Results of the economic analysis: total average costs and QALYs per user under contingency management or standard care, over a year of follow-up

Intervention	Average total cost (NHS/PPS)	Average total cost (NHS/PPS plus crime- related)	Average number of QALYs	ICER of CM versus standard care
CM	£2,733	£28,822	0.71	£15,219/QALY
Standard care	£2,341	£28,820	0.68	(NHS/PPS) £74/QALY
Difference	£392	£2	0.03	(NHS/PPS plus crime-related)

perspective and £74 per QALY from a wider perspective including criminal justice system and crime victim costs. Full results of the analysis are provided in Table 46.

SENSITIVITY ANALYSIS

From an NHS/PPS perspective, results were sensitive to changes in the RRs of the percentage abstinence achieved by users receiving contingency management versus standard care. When the lower 95% CIs of all estimated RRs were used, the ICER of contingency management versus standard care became £68,283 per QALY. It must be noted, however, that the base-case results were robust under changes in the RRs of abstinence rates referring to the 12-week intervention period only (that is, when RRs of abstinence rates achieved at follow-up remained intact). In this case, the ICER of contingency management versus standard care was £16,219 per QALY, which is below the NICE-set cost-effectiveness threshold of £20,000 per QALY (NICE, 2005b). It was therefore the uncertainty characterising the follow-up data used in the analysis that strongly affected the results.

The ICER was robust in changes in the value of reinforcing vouchers, in the use of lowest and highest estimates of healthcare costs reported in Godfrey and colleagues (2002), as well as in the exclusion of these costs.

When a wider perspective that included crime-related costs was considered (non-reference case analysis), contingency management was cost effective (that is, its ICER versus standard care was below £20,000 per QALY) under all scenarios explored.

Full results of the one-way sensitivity analysis are provided in Table 47.

Input parameter varied	Results – NHS/PSS analysis	Results – non-reference case analysis
RRs of abstinence -Lower 95% CIs -Upper 95% CIs	£68,283/QALY £6,862/QALY	£248/QALY CM dominates standard care
Costs of vouchers -100% increase -50% decrease	£15,959/QALY £14,850/QALY	£813/QALY CM dominates standard care
Additional healthcare and crime-related costs —Lowest estimates —Highest estimates	£15,201/QALY £15,266/QALY	£2,584/QALY CM dominates standard care
Exclusion of additional healthcare and crimerelated costs	£15,126/QALY	N/A
Exclusion of crime victim costs	N/A	£16,222/QALY

Table 47: Results of sensitivity analysis

Limitations of the economic analysis and overall conclusions

The results of the analysis are subject to various limitations. In order to utilise the available efficacy data, a number of assumptions were required. It was assumed that people who misuse drugs had only one period of consecutive weeks of abstinence, as only one (that is, the longest) such period was recorded for every user in the trials considered in the analysis. This assumption is likely to have underestimated the effectiveness of both contingency management and standard care. Follow-up data on abstinence were limited and referred to two time points only: at the end of the intervention period (12 weeks) and at 6 months. Weekly abstinence rates between 12 and 52 weeks were estimated and/or extrapolated from these data. In order to construct the economic model it was assumed that, at follow-up, once people in treatment were found to misuse drugs, they continued misusing drugs and did not achieve abstinence thereafter. This assumption may not accurately reflect abstinence trends among users over time.

Intervention costs were based on GDG estimates of relevant resource use, owing to lack of research-based data. Other healthcare costs, as well as crime-related costs that were included in the non-reference case analysis, were derived from Godfrey and colleagues (2002), who estimated such costs based on UK resource use data. According to the study, these costs depended exclusively on retention of people who misuse drugs in treatment, and were not affected by levels of abstinence achieved through treatment. This is a rather conservative assumption, at least in the longer term. If remaining abstinent for longer periods reduces healthcare resource use and costs related to crime, then the cost effectiveness of contingency management is greater than that estimated in this analysis, since it is more effective than standard care in achieving higher rates and longer periods of abstinence. On the other hand, evidence suggests that retention in treatment is not significantly different between contingency management and standard care. Consequently, healthcare and crime-related costs should be similar for people who misuse drugs under any of the two treatment options, if such costs exclusively depend on retention in treatment.

Long-term healthcare costs incurred by drug misuse, such as costs associated with infectious disease risks among people injecting drugs, were not considered in the economic analysis, as no data were available in the literature. However, some of these costs have already been taken into account in the estimation of healthcare costs of people who misuse drugs reported by Godfrey and colleagues (2002). Costs related to neonatal care of infants born to mothers who misuse cocaine and/or opioids were not estimated, and there is evidence that such costs may impose a significant economic burden on the health services (Godfrey *et al.*, 2002; Behnke *et al.*, 1997; Chiu *et al.*, 1990; Joyce *et al.*, 1995; Norton *et al.*, 1996; Phibbs *et al.*, 1991; US General Accounting Office, 1990). Voluntary sector costs, social services costs and productivity losses were not included in the analysis. If all these cost elements are expected to be lower when higher rates of abstinence are achieved, then contingency management is likely to be more cost effective than the findings of the analysis suggest.

Contingency management was shown to be a cost-effective option under most scenarios explored from an NHS/PPS perspective. Results were only sensitive to the

uncertainty characterising the effectiveness data at 6-month follow-up. On the other hand, when a wider perspective including criminal justics and crime victim costs was considered, contingency management was cost effective under all scenarios tested in the sensitivity analysis. In conclusion, despite the limitations of the economic analysis, the results indicate that contingency management is likely to be a cost effective option for people who misuse cocaine and opioids undergoing methadone maintenance treatment, especially when the wider economic, social and public health consequences of drug misuse are considered.

8.4.10 Clinical practice recommendations

- 8.4.10.1 Drug services should introduce contingency management programmes as part of the phased implementation programme led by the NTA to reduce illicit drug use and/or promote engagement with services for people receiving methadone maintenance treatment.
- 8.4.10.2 Contingency management aimed at reducing illicit drug use for people receiving methadone maintenance treatment or who primarily misuse stimulants should be based on the following principles.
 - The programme should offer incentives (usually vouchers that can be exchanged for goods or services of the service user's choice, or privileges such as take-home methadone doses) contingent on each presentation of a drug-negative test (for example, free from cocaine or non-prescribed opioids).
 - If vouchers are used, they should have monetary values that start in the region of £2 and increase with each additional, continuous period of abstinence.
 - The frequency of screening should be set at three tests per week for the first 3 weeks, two tests per week for the next 3weeks, and one per week thereafter until stability is achieved.
 - Urinalysis should be the preferred method of testing but oral fluid tests may be considered as an alternative.
- 8.4.10.3 Staff delivering contingency management programmes should ensure that:
 - the target is agreed in collaboration with the service user
 - the incentives are provided in a timely and consistent manner
 - the service user fully understands the relationship between the treatment goal and the incentive schedule
 - the incentive is perceived to be reinforcing and supports a healthy/drug-free lifestyle.
- 8.4.10.4 Drug services should ensure that as part of the introduction of contingency management, staff are trained and competent in appropriate near-patient testing methods and in the delivery of contingency management.
- 8.4.10.5 Contingency management should be introduced to drug services in the phased implementation programme led by the NTA, in which staff training and the development of service delivery systems are carefully evaluated.

Psychological interventions

- The outcome of this evaluation should be used to inform the full-scale implementation of contingency management.
- 8.4.10.6 Behavioural couples therapy should be considered for people who are in close contact with a non-drug-misusing partner and who present for treatment of stimulant or opioid misuse (including those who continue to use illicit drugs while receiving opioid maintenance treatment or after completing opioid detoxification). The intervention should:
 - focus on the service user's drug misuse
 - consist of at least 12 weekly sessions.
- 8.4.10.7 All interventions for people who misuse drugs should be delivered by staff who are competent in delivering the intervention and who receive appropriate supervision.

8.4.11 Research recommendations – contingency management

Implementation of contingency management

8.4.11.1 Which methods of implementing contingency management (including delivering and stopping incentives) and which settings (including legally coerced, community-based and residential) – compared with one another and with standard care – are associated with the longest periods of continued abstinence and reduced drug misuse, and with maintenance of abstinence/reduction of drug misuse at follow-up?

Why this is important

Although the efficacy of contingency management for drug misuse has been extensively investigated, there is a lack of large-scale and well-conducted implementation studies. The implementation of contingency management programmes in the UK would be aided by research assessing specific components of the programme.

Testing within contingency management programmes

8.4.11.2 For people who misuse drugs and who are participating in contingency management, which method of testing – urinalysis, sweat analysis or oral fluid analysis – is most sensitive, specific, cost effective and acceptable to service users?

Why this is important

There is a lack of data comparing the sensitivity and specificity, cost effectiveness and acceptability to service users of these methods of testing. Identifying drug use during treatment is an important aspect of contingency management; identifying which testing methods are the most effective is important for health and social care services intending to implement contingency management programmes.

8.5 PSYCHOLOGICAL INTERVENTIONS IN COMBINATION WITH NALTREXONE MAINTENANCE TREATMENT

8.5.1 Introduction

Naltrexone is an opioid antagonist that blocks the euphoric and other effects of opioids, and therefore eliminates the positive rewards associated with opioid use. A recent health technology appraisal conducted by NICE (2006c) concluded that naltrexone may have some limited benefit in helping those who have been detoxified from opioids in remaining abstinent, although very limited evidence also suggests naltrexone to be more effective in individuals who are highly motivated. The health technology appraisal acknowledged that naltrexone loses its protective effect if the service user does not take the medication, and also recommended that people who are prescribed naltrexone engage in psychosocial interventions, such as counselling and self-help groups, that promote concordance with medication. However, the evidence presented suggests that only contingency programmes providing incentives for individuals to remain abstinent have a positive impact on naltrexone concordance and other outcomes. A central question is whether the wider evidence base for psychosocial interventions substantiates the recommendation in the health technology appraisal.

Naltrexone is not widely used in the UK, accounting for only 11,000–14,000 prescriptions per annum, not all of which would be for managing opioid dependence (NICE, 2006c). Where it is prescribed, it is not evident whether this is done as part of a comprehensive package of care that includes psychological intervention and general support.

8.5.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline is in Table 48.

8.5.3 Studies considered¹²

The review team conducted a new systematic search for RCTs that assessed the efficacy of contingency management, interpersonal therapy, CBT, behavioural couples therapy (BCT), and psychodynamic and family-based interventions in combination with naltrexone maintenance treatment (see Table 49).

¹²Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 48: Databases searched and inclusion/exclusion criteria for clinical effectiveness of psychological interventions in combination with naltrexone maintenance treatment

Electronic databases	MEDLINE, EMBASE, PsycINFO, HMIC, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who are undergoing naltrexone maintenance treatment for opioid dependence
Interventions	Opioid antagonist treatment: naltrexone Psychological interventions: CM, CBT, family-based interventions, psychodynamic interventions
Outcomes	Abstinence: point abstinence, duration of abstinence Illicit drug use: frequency of using illicit drugs over a period Concordance with naltrexone: number of doses or days taken

In the review of naltrexone in combination with contingency management, three trials (CARROLL2001B; CARROLL2002; PRESTON1999) met the eligibility criteria, providing data on 171 participants. All trials were published in peer-reviewed journals.

For naltrexone in combination with relapse-prevention CBT, two trials (RAWSON2001; TUCKER2004B) met the guideline eligibility criteria, providing data on 253 participants. All trials were published in peer-reviewed journals.

For naltrexone in combination with family-based interventions, two trials (CARROLL2001B; FALS-STEWART2003) met the eligibility criteria, providing data on 216 participants. All trials were published in peer-reviewed journals.

In addition, two studies were excluded from the analysis. The most common reason for exclusion was poor study quality (further information about both included and excluded studies can be found in Appendix 14). Forest plots and full evidence profiles are provided in Appendix 15 and 16 respectively.

Table 49: Study information and summary evidence table for trials of psychological interventions in combination with naltrexone versus control

	Naltrexone + CM versus naltrexone + standard care	Naltrexone + relapse- prevention CBT versus naltrexone + standard care	Naltrexone + family-based interventions versus naltrexone + standard care
Total no. of trials (total no. of participants)	3 RCTs $(N = 172)$	$ 2 \text{ RCTs} \\ (N = 253) $	2 RCTs (N = 216)
Study ID	CARROLL2001B CARROLL2002 PRESTON1999	RAWSON2001 TUCKER2004B	CARROLL2001B FALS-STEWART2003
Problem drug or diagnosis	Opioid dependence	Opioid dependence	Opioid dependence
Treatment length	12 weeks: CARROLL2001B CARROLL2002 PRESTON1999	12 weeks: TUCKER2004B 52 weeks: (RAWSON2001)	12 weeks: CARROLL2001B 24 weeks: FALS-STEWART2003
Length of follow-up	3 to 6 months	3 to 12 months	12 months
Age (years)	32 to 33	30 to 33	33 to 34
Evidence profile table number (Appendix 16)	Table A16-25	Table A16-27	Table A16-26
Overall quality of evidence	Moderate	Moderate	Moderate
Concordance with naltrexone	Days/doses used: SMD -0.44 (-0.75 to -0.13), K = 3, N = 171	Days/doses used: SMD -0.74 (-1.19 to -0.29), K = 1, N = 81	Days/doses used: SMD -0.46 (-0.73 to -0.19), K = 2, N = 216

Table 49: (Continued)

	Naltrexone + CM versus naltrexone + standard care	Naltrexone + relapse- prevention CBT versus naltrexone + standard care	Naltrexone + family-based interventions versus naltrexone + standard care
Durations of abstinence	Cocaine Longest duration: SMD -0.32 $(-0.67 \text{ to } 0.03)$, $K = 2$, $N = 133$ Proportion days abstinent: SMD -0.07 $(-0.52 \text{ to } 0.37)$, $K = 1$, $N = 77$ Opioids Longest duration: SMD -0.41 $(-0.76 \text{ to } -0.05)$, $K = 2$, $N = 133$ Proportion days abstinent: SMD -0.32 $(-0.77 \text{ to } 0.12)$, $K = 1$, $N = 77$	Cocaine 3 weeks: RR 1.46 (1.02 to 2.10), K = 1, N = 81 8 weeks: RR 2.38 (1.26 to 4.53), Froportion days abstinent: SMI Cocaine Cocaine Cocaine Cocaine Cocaine Cocaine Co.84 to -0.01, K = 1, N = 16	Cocaine Longest duration: SMD -0.43 $(-0.84 \text{ to } -0.01)$, $K = 1$, $N = 92$ Proportion days abstinent: SMD -0.38 $(-0.65 \text{ to } -0.11)$, $K = 2$, $N = 216$ Opioids Longest duration: SMD -0.45 $(-0.86 \text{ to } -0.03)$, $K = 1$, $N = 92$ Proportion days abstinent: SMD -0.45 -0.43 $(-0.70 \text{ to } -0.16)$, $K = 2$, $N = 216$
Point abstinence	I	Negative urine or self-report: Endpoint: RR 1.13 (0.62 to 2.05), $K = 1$, $N = 81$	I
Illicit drug use	ı	Days' heroin use in past month: Endpoint: SMD - 0.16 (-0.58 to 0.26), K = 1, N = 88 3-month follow-up: SMD 0.13 (-0.30 to 0.56), K = 1, N = 84	I
Mortality	I	RR 0.98 (0.14 to 6.59), K = 1, N = 81	ı

8.5.4 Psychosocial interventions in combination with naltrexone maintenance treatment

A recent NICE technology appraisal (NICE, 2007) concluded that psychosocial interventions should be provided for people undertaking naltrexone maintenance treatment in order to increase adherence to this medication. This section of the guideline assesses the efficacy of such psychosocial interventions in greater detail. The study information and summary evidence is in Table 49.

8.5.5 Clinical summary

Contingency management, behavioural couples therapy and family-based interventions were all associated with significantly improved outcomes during treatment, but there is very limited follow-up data in any of the six trials and no evidence of long-term benefit.

There were mixed results for CBT. The trial with a 52-week duration appeared to be effective, although a more recent 12-week trial did not appear to affect drug use.

Given the recommendation in the NICE technology appraisal for a specific psychosocial intervention to support the use of naltrexone (which currently has a very low rate of uptake in the NHS), current evidence would suggest that service user and clinician preference, and whether the service user is in close contact with a partner or family member, should direct the choice of contingency management, behavioural couples therapy and family-based interventions.

8.5.6 Clinical practice recommendation

- 8.5.6.1 For people receiving naltrexone maintenance treatment to help prevent relapse to opioid dependence, staff should consider offering:
 - contingency management to all service users (based on the principles described in recommendations 1.4.1.3 and 1.4.1.4)
 - behavioural couples therapy or behavioural family interventions to service users in close contact with a non-drug-misusing family member, carer or partner (based on the principles described in recommendation 1.4.3.1 for behavioural couples therapy).

8.6 SELF-HELP GROUPS

8.6.1 Introduction

There is a long tradition in North America and Europe of self-help groups for people who misuse drugs. Most of these offer a programme of recovery known as the 12-steps, which has its origins in AA. Self-help groups especially relevant to people who misuse drugs are Narcotics Anonymous (NA) and Cocaine Anonymous (CA). There

are other self-help groups available that offer alternative philosophies and approaches, but these have not taken root in the UK to the same extent as 12-step groups. There is open access to groups; the only entry requirement is for individuals to acknowledge that they have a drug problem. In principle, individuals may attend simply with the desire to become abstinent. It is not a requirement to be drug free at first attendance nor to abstain from the prescribed use of medication (including methadone maintenance), although in practice disapproval of opioid maintenance treatment is not uncommon among some 12-step communities.

There have been few research studies into the acceptability of the 12-step programme among UK drug users; however, a series of studies conducted in London NHS inpatient detoxification services (for example, Best *et al.*, 2001) suggested that people who were drug dependent reported more positive attitudes to NA/AA and to the 12-step programme than those who were alcohol dependent, and reported a greater intention to attend after detoxification.

Current practice

Over the past 15 years, there has been a marked increase in availability of self-help group meetings in the UK. In 2003, there were approximately 500 regular NA group meetings nationwide; by 2006, this had risen to 800 (NA, 2006). Many individuals will make use of self-help groups without first having contact with statutory drug services, either self-referring or attending following advice from a non-drug specialist such as a GP or other member of the primary care team.

One of the limitations of the literature reviewed below is the lack of UK studies, with the majority of studies on 12-step self-help groups conducted in the US. However, the growth of NA in the UK suggests that there is some acceptability of this resource among people who misuse drugs.

8.6.2 Definitions of interventions

Self-help group

A group of people who misuse drugs meet regularly to provide help and support for one another. The group is typically community based, peer led and non-professional.

12-step self-help group

A non-profit fellowship of people who meet regularly to help each other remain abstinent. The core of the 12-step programme is a series of 12 steps that include admitting to a drug problem, seeking help, self-appraisal, confidential self-disclosure, making amends – when possible – where harm has been done, achieving a spiritual awakening and supporting other drug-dependent people who want to recover.

8.6.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline is in Table 50.

Table 50: Databases searched and inclusion/exclusion criteria for clinical effectiveness of self-help interventions

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT Observational studies
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	Self-help 12-step self-help groups
Outcomes	Abstinence: point abstinence, duration of abstinence Illicit drug use: frequency of using illicit drugs over a period of time

The review team conducted a systematic search for RCTs and observational studies that assessed the efficacy of 12-step self-help groups. Seven studies met the inclusion eligibility criteria set by the GDG. Two were RCTs (McAuliffe, 1990; Timko *et al.*, 2006), two were cohort studies (Moos *et al.*, 1999; Ethridge *et al.*, 1999), one was a prospective longitudinal study (Fiorentine & Hillhouse, 2000), one was a case series (Toumbourou *et al.*,2002) and one was a sub-analysis of self-help group participation in all groups of an RCT (Weiss *et al.*, 2005). All studies were published in peer-reviewed journals.

In addition, 16 studies were excluded from the analyses. The most common reason for exclusion was diagnosis of comorbid psychosis.

8.6.4 Benefits of attendance at self-help groups

The majority of studies on self-help groups have looked at 12-step-based groups. Various studies show that 12-step involvement has a positive impact on outcomes. For example, Weiss and colleagues (2005) show that, while simple attendance did not predict drug use, active participation in self-help groups did predict lower cocaine use in the following month and increasing levels of participation produced a significant incremental benefit. Similar associations between NA attendance and improved druguse outcomes are reported by Fiorentine and Hillhouse (2000). Four hundred and seventeen participants commencing outpatient substance misuse treatment had an intake interview and 8 months later a follow-up interview, in order to determine the relationship between drug treatment participation and 12-step involvement. Overall findings

illustrate that individuals who regularly attended 12-step programmes prior to treatment had significantly higher rates of successful treatment completion. Fiorentine and Hillhouse (2000) also demonstrate an additive effect of engaging in treatment and a 12-step self-help group at the same time, as this results in significantly better treatment outcomes when compared with drug treatment or 12-step self-help group participation alone. In Australia, Toumbourou and colleagues (2002) conducted interviews with 91 new members entering NA self-help groups. At baseline, participants filled in questionnaires regarding sociodemographic status and attendance levels at 12-step self-help groups in the year prior to the first interview. At 12-month follow-up, they completed a second interview detailing levels of involvement, highest step completed and levels of weekly attendance at the self-help groups. Self-report measures indicated that higher and more stable levels of NA involvement were associated with less marijuana and hazardous alcohol use.

McAuliffe (1990) conducted an RCT comparing a recovery training and self-help programme with a control condition. The recovery training and self-help group received a combined programme of professionally led recovery skills workshops and weekly self-help group meetings (not 12-step). Improved drug-use outcomes were shown at 6 and 12 months in both a US and a Hong Kong sample. This may indicate that non-12-step self-help groups are also beneficial in reducing relapse.

There is consistent evidence that 12-step attendance mediates better substance misuse outcomes. However, it should be noted that in most studies reviewed above, attendance at self-help groups was assessed alongside other treatment programmes. Although there are clear associations between self-help group attendance and drug-use outcomes, the impact of self-help groups outside intensive treatment programmes has not been assessed in enough detail.

8.6.5 Facilitating self-help group affiliation

A variety of studies have assessed interventions that encourage self-help group affiliation. These interventions range from 'intensive referral', providing advice, information and a personal contact (Timko *et al.*, 2006), to residential programmes with a strong 12-step focus.

A large-scale prospective cohort study (n = 3,018) conducted by Moos and colleagues (1999) revealed that people receiving 12-step-based treatment for drug and/or alcohol misuse had superior abstinence outcomes compared with those in CBT or eclectic (based on a combination of 12-step and CBT principles) treatment groups. Humphreys and colleagues (1999) sought to further investigate the relationship between post-treatment self-help group participation and abstinence. They suggest that the level of participation in self-help groups may mediate the relationship between self-help group involvement and abstinence; that is, those receiving 12-step-based treatment were more highly involved in the programme than those in either CBT or eclectic treatment programmes; thus, increased levels of participation may have facilitated positive outcomes.

Timko and colleagues (2006) investigated the effects of intensive versus standard referral to self-help groups (based on the 12-step model), in order to determine which

method increased self-help group attendance over a 6-month period. Participants commencing substance misuse outpatient treatment were randomly assigned to either group; those in the standard referral group received a timetable of local meetings. Participants in the intensive referral group received the same material as those in the standard group, with the addition of an information pack detailing various aspects of 12-step meetings and a more intensive discussion of the benefits, and potential concerns, of attending 12-step meetings. They were required to keep a record of self-help group meetings they attended and give brief descriptions of their personal reactions to and thoughts regarding the meeting. Counsellors also arranged for the participants to meet a self-help group volunteer who would accompany them to their first meeting. At 6 months' follow-up, the intensive referral group showed greater attendance of and participation in self-help groups compared with those in the standard referral group. Furthermore, those in the intensive referral group showed greater reduction in alcohol and drug use and were more likely to be abstinent compared with those in the standard referral group.

Ouimette and colleagues (1998), in a secondary analysis of the study by Moos and colleagues (1999), showed that there was a synergistic effect between outpatient aftercare provision and 12-step self-help group participation following treatment. Service users who participated in both did better than those who only participated in one or the other. Those who did neither had the poorest outcomes. Once again, this study showed that increased frequency of attendance and increased involvement in 12-step activities enhanced outcomes.

8.6.6 Clinical summary

There have been several studies assessing the use of self-help groups for people who misuse drugs. The majority of studies have been conducted on 12-step programmes. There is limited but consistent evidence from these studies that 12-step attendance is associated with abstinence from illicit drugs and alcohol, and fewer drug and alcohol problems. Furthermore, involvement in such programmes can be improved by interventions from healthcare professionals to encourage regular attendance and active participation in such groups.

8.6.7 Clinical practice recommendations

- 8.6.7.1 Staff should routinely provide people who misuse drugs with information about self-help groups. These groups should normally be based on 12-step principles; for example, Narcotics Anonymous and Cocaine Anonymous.
- 8.6.7.2 If a person who misuses drugs has expressed an interest in attending a 12-step self-help group, staff should consider facilitating the person's initial contact with the group, for example by making the appointment, arranging transport, accompanying him or her to the first session and dealing with any concerns.

8.7 COORDINATION OF CARE AND CASE MANAGEMENT

8.7.1 Introduction

This section focuses on the evidence for the use of psychological interventions as part of broader packages of care, in particular case management. Case management is a strategy to improve the coordination of care for people who misuse drugs. It was devised for people with complex and multiple needs. An individual worker, the case manager, is responsible for the coordination and, where necessary, provision of care for service users. Contact with the case manager is usually expected to be on a regular ongoing basis. Case management originated in the mental health field and since the early 1980s it has been used in substance misuse services, mostly in the US but also in some European countries (in particular the Netherlands and Belgium).

In UK practice, case management has not been applied systematically in the same way as it has in the US and other European countries. The closest to case management in the UK is the care planning and care coordination approach, which have recently been the focus of much attention from the NTA and the subject of the recent Health Commission and NTA review of services, establishing these as important areas for development in UK services (NTA, 2006a). One of the conclusions of this review is that there is wide variation in procedures across the country.

8.7.2 Definitions of interventions

Case management

There is no unified definition of case management, and programmes vary depending on clinical populations and treatment systems. The guiding principle, consistent with a long-term view of drug problems, is that of coordinating episodes of care both over time and across health and social care systems. In practice, a case manager works with the service user in order to enrol the service user in the required services and coordinate the various services required for the complex array of problems.

Intensive referral

This intervention aims to engage service users in treatment via an initial needs assessment and referral session, but does not provide the element of ongoing contact that is considered here as characteristic of case management.

Standard referral

Service users are provided with a list of contact details and are expected to make their own appointments.

8.7.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline is in Table 51.

Table 51: Databases searched and inclusion/exclusion criteria for clinical effectiveness of case management

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	Case management, intensive referral, care coordination
Outcomes	Abstinence: point abstinence, duration of abstinence Drug use: frequency of using illicit drugs over a period of time

8.7.4 Studies considered¹³

The review team conducted a new systematic search for RCTs that assessed the efficacy of case management (see Table 52). For trials of intensive referral versus standard referral, two RCTs (STRATHDEE2006; ZANIS1996) met the eligibility criteria, providing data on 286 participants. For trials of case management with ongoing contact versus standard care, eight RCTs (COVIELLO2006; MARTIN1993; MEJTA1997; MORGENSTERN2006; NEEDELS2005: Study 1; NEEDELS2005: Study 2; SALEH2002; SORENSEN2005) met the eligibility criteria providing data on 2,623 participants. All trials were published in peer-reviewed journals.

In addition, five studies were excluded from the analysis. The most common reason for exclusion was not providing required outcomes (further information about both included and excluded studies can be found in Appendix 14).

8.7.5 Case management

A summary of study information and evidence from the included trials is provided in Table 52 and Table 53. For further details of forest plots and full evidence profiles see Appendix 15 and 16.

¹³Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

Table 52: Study information table for trials of case management for people who misuse drugs

	Intensive referral versus standard care for people not in formal drug treatment	Case management (with ongoing contact) versus standard care for people not in formal drug treatment
Total no. of trials (total no. of participants)	2 RCTs (N = 286)	8 RCTs (N = 2,623)
Study ID	STRATHDEE2006 ZANIS1996	COVIELLO2006 MARTIN1993 MEJTA1997 MORGENSTERN2006 NEEDELS2005: Study 1 NEEDELS2005: Study 2 SALEH2002 SORENSEN2005
Problem drug or diagnosis	Injection drug use: STRATHDEE2006 (100%) Opioid dependence	Any drug misuse in past 6 months: NEEDELS2005 (87%) History of drug use
	(seeking MMT): STRATHDEE2006	associated with HIV risk: MARTIN1993 (100%)
	(100%), ZANIS1996 (100%)	Any substance dependence (DSM-IV): MORGENSTERN 2006 (100%; 33% primarily alcohol)
		Seeking residential substance misuse treatment: SALEH2002 (100%)
		Opioid dependence: COVIELLO2006 (100%), MEJTA1997 (100%), SORENSEN2005 (100%)
Treatment length	1 week: STRATHDEE2006 2 weeks: ZANIS1996	6 weeks: COVIELLO2006 6 months: MARTIN1993, SORENSEN2005 12 months: SALEH2002 15 months: MORGENSTERN2006 36 months: MEJTA1997
Length of follow-up	Up to 2 weeks	Up to 3 years
Age (years)	41 to 42	17 to 45

Table 53: Summary evidence table for trials of case management for people who misuse drugs*

	Intensive referral versus standard care for people not in formal drug treatment	Case management versus standard care for people not in formal drug treatment
Total no. of trials (total no. of participants)	2 RCTs (N = 286)	8 RCTs (N = 2,623)
Study ID	STRATHDEE2006 ZANIS1996	COVIELLO2006 MARTIN1993 MEJTA1997 MORGENSTERN2006 NEEDELS2005: Study 1 NEEDELS2005: Study 2 SALEH2002 SORENSEN2005
Evidence profile table number (Appendix 16)	Table A16–29	Table A16–28
Overall quality of evidence	Moderate	Moderate
Durations of abstinence	_	Drug-free days per month: SMD -0.13 (-0.47 to 0.20), K = 1, N = 140
Point abstinence at follow-up		Cannabis: RR 1.14 (0.97 to 1.35), K = 3, N = 1,538 Cocaine: RR 1.26 (0.81 to 1.98), K = 3, N = 1,538 Opioids: RR 1.34 (0.63 to 2.87), K = 2, N = 192 All drugs: RR 1.16 (0.59 to 2.31), K = 2, N = 565
Initiation of treatment	Started any treatment: RR 2.92 (0.52 to 16.35), K = 2, N = 286	Started any treatment: RR 1.34 (1.04 to 1.72), $K = 4$, $N = 2,028$ Time taken to enter treatment: SMD -1.63 (-1.88 to -1.37), $K = 1$, $N = 316$

Continued

Table 53: (Continued)

	Intensive referral versus standard care for people not in formal drug treatment	Case management versus standard care for people not in formal drug treatment
Retention in treatment	_	In treatment at follow-up: RR 1.20 (0.84 to 1.74), K = 3, N = 1,530
		Completed at least one outpatient programme: RR 1.92 (1.35 to 2.72), K = 1, N = 302
		Retained in any treatment for at least 3 months: RR 2.29 (1.55 to 3.39), K = 1, N = 302
		Time retained in treatment: SMD -0.93 (-1.16 to -0.70), K = 1, N = 316

^{*}RR > 1 favours intervention, negative SMD values favour intervention.

8.7.6 Clinical summary

One of the difficulties when interpreting this evidence is the variation in the sample populations, as well as what constitutes 'case management' in different studies.

Bearing in mind these sources of variation, overall, the evidence available consistently suggests that both intensive referral and case management, whether limited to a 'brief' care planning session, or initial care planning with ongoing contact, is effective at engaging service users in treatment at different stages of the treatment process. In terms of effects on illicit drug use, however, the evidence is mixed, with the overall suggestion of the meta-analysis that there is no improvement in outcomes compared with standard care.

While all the studies reviewed are US-based and hence interpretation should consider the cultural and health system differences already outlined, it should be noted that a remarkably similar picture is presented in mainstream mental health contexts in the UK and US, in that case management tends to improve treatment engagement but does not itself necessarily make a difference to outcomes (for example, for schizophrenia; NICE, 2002). The current evidence implies that for people who misuse drugs, effective, structured psychological interventions must be delivered in addition to standard care planning in order to achieve improved outcomes.

8.7.7 Clinical practice recommendation

8.7.7.1 In order to reduce loss of contact when people who misuse drugs transfer between services, staff should ensure that there are clear and agreed plans to facilitate effective transfer.

8.8 MULTI-MODAL CARE PROGRAMMES

8.8.1 Introduction

Multi-modal care programmes for the purpose of this review are defined as including a combination of therapy activities delivered in intensive schedules of 10 hours per week or more. Content of these programmes varies but would usually include education, daily living skills and other psychologically based interventions (for example, CBT, relapse prevention and reinforcement-based approaches), mostly delivered in group format. Such programmes are not common in generic drug treatment services in the UK, although they are available in some areas. They are more commonly used within drug services linked to the criminal justice system as a way of providing more intensive programmes for those referred. The current use of these interventions in the UK is limited and their distribution is not well understood.

8.8.2 Definitions of interventions

Standard outpatient treatment

Treatment occurs in regularly scheduled sessions typically totalling 1–2 hours per week. Examples include weekly or twice-weekly individual therapy, weekly group therapy or a combination of the two.

Extended outpatient treatment

Outpatient treatment as above, but with up to 9 contact hours per week, typically involving additional group work (group therapy, educational groups and/or self-help groups).

Intensive outpatient treatment

Healthcare professionals provide several treatment components to service users. Treatment consists of regularly scheduled sessions within a structured programme, with a minimum of 9 contact hours per week (ASAM, 2001).

Intensive outpatient treatment with reinforcement-based treatment

Intensive outpatient treatment as above, but with additional benefits (such as the right to undertake vocational training and/or paid work) contingent on providing a drug-free urine sample.

Psychological interventions

Structured day treatment

Structured day treatment provides intensive community-based support, treatment and rehabilitation. Clear programmes of defined activities should be offered for a fixed period of time with specified attendance criteria, usually 4–5 days (20 hours total) per week (NTA, 2002).

8.8.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 54.

Table 54: Databases searched and inclusion/exclusion criteria for clinical effectiveness of multi-modal care programmes

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who misuse opioids, stimulants, cannabis; polydrug misuse
Interventions	Intensive outpatient treatment, reinforcement-based intensive and extended outpatient treatment, day treatment
Outcomes	Abstinence: point abstinence, duration of abstinence Illicit drug use: frequency of using illicit drugs over a period of time

8.8.4 Studies considered¹⁴

The review team conducted a new systematic search for RCTs that assessed the efficacy of multi-modal care programmes (see Table 55).

In the review of intensive outpatient treatment, four trials (COVIELLO2001; MCLELLAN1993; VOLPICELLI2000; WEINSTEIN1997) met the eligibility criteria providing data on 717 participants. All trials were published in peer-reviewed journals.

¹⁴Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

In the review of day treatment, two trials (AVANTS1999, MARLOWE2003) met the guideline eligibility criteria providing data on 370 participants. All trials were published in peer-reviewed journals.

In the review of intensive outpatient treatment with reinforcement-based therapy, three trials (JONES2005, SILVERMAN2001, SILVERMAN in press) met the eligibility criteria providing data on 282 participants. Two trials were published in peerreviewed journals and one was in press. For further details on included studies see Appendix 14.

8.8.5 Multi-modal treatment programmes

Table 55 and Table 56 summarise study information and evidence for multi-modal treatment programmes. For further details see appendix 15 and 16 for forest plots and full evidence profiles.

8.8.6 Clinical summary

The evidence related to intensive outpatient treatments and day treatments (defined respectively as at least 9 and 20 hours of group work per week) does not support the notion that 'more is better' when comparing more intensive treatments to standard outpatient treatment in relation to drug-use outcomes. There is some evidence that reinforcement-based treatment can improve drug-use outcomes, although real-world application of this type of intervention may be limited. It is important to note, however, that some of the standard practice in the US appears to be better structured and more intensive than routine outpatient UK practice.

8.9 VOCATIONAL INTERVENTIONS

8.9.1 Introduction

People who misuse drugs often experience high rates of unemployment (Crowther *et al.*, 2001). Crowther and colleagues (2001) argue that there are a number of social and clinical reasons for helping people with serious mental illness to work that are also applicable to people who misuse drugs. From a social standpoint, high unemployment rates are an index of the social exclusion of people who misuse drugs. From a clinical standpoint, employment may lead to improvements in the outcomes of people who misuse drugs through increasing self-esteem, alleviating psychiatric symptoms, and reducing dependency and relapse.

Table 55: Study information table for trials of intensive outpatient treatment, day treatment and reinforcement-based therapy

	Intensive outpatient treatment versus standard outpatient treatment	Intensive outpatient treatment versus extended outpatient treatment	Day treatment versus standard outpatient treatment	Intensive outpatient treatment with reinforcement- based therapy versus standard care
Total no. of trials (total no. of participants)	3 RCTs $(N = 623)$	1 RCT (N = 94)	2 RCTs (N = 370)	3 RCTs $(N = 282)$
Study ID	MCLELLAN1993 VOLPICELLI2000 WEINSTEIN1997	COVIELLO2001	AVANTS1999 MARLOWE2003	JONES2005 SILVERMAN2001 SILVERMANin press
Problem drug or diagnosis	Cocaine dependence (DSM-III-R/IV): VOLPICELLI2000 WEINSTEIN1997	Cocaine dependence (DSM-III-R/IV)	Cocaine dependence (DSM-III-R/IV): MARLOWE2003	Opioid dependence (MMT)
	Opioid dependence (MMT): MCLELLAN1993		Opioid dependence (MMT): AVANTS1999	
Treatment length	3 months: WEINSTEIN1997 6 months: MCLELLAN1993 12 months: VOLPICELLI2000	1 month	3 months: AVANTS1999 4 months: MARLOWE2003	6 months
Length of follow-up	Up to 9 months	7 months	Up to 6 months	0 to 12 months
Age (years)	32 to 41	40	34 to 36	38 to 45

Table 56: Summary evidence table for trials of intensive outpatient treatment, day treatment and reinforcement-based therapy

	Intensive outpatient treatment versus standard outpatient treatment	Intensive outpatient treatment versus extended outpatient treatment	Day treatment versus standard outpatient treatment	Intensive outpatient treatment with reinforcement- based therapy versus standard care
Total no. of trials (total no. of participants)	3 RCTs $(N = 623)$	1 RCT (N = 94)	$ 2 \text{ RCTs} \\ \text{(N = 370)} $	3 RCTs $(N = 282)$
Study ID	COVIELLO2001 MCLELLAN1993 VOLPICELLI2000 WEINSTEIN1997	COVIELLO2001	AVANTS1999 MARLOWE2003	JONES2005 SILVERMAN2001 SILVERMANin press
Evidence profile table number (Appendix 16)	Table A16-30	Table A16-31	Table A16-32	Table A16-33
Overall quality of evidence	Moderate	Moderate	Moderate	Moderate

Table 56: (Continued)

	Intensive outpatient treatment versus standard outpatient treatment	Intensive outpatient treatment versus extended outpatient treatment	Day treatment versus standard outpatient treatment	Intensive outpatient treatment with reinforcement- based therapy versus standard care
Durations of abstinence	Cocaine (secondary to MMT) Continuous duration: 8 weeks: RR 1.02 (0.81 to 1.28), K = 1, N = 67 16 weeks: RR 1.28 (0.67 to 2.46), K = 1, N = 67 Opioids Continuous duration: 8 weeks: RR 0.91 (0.76 to 1.10), K = 1, N = 67 16 weeks: RR 1.94 (0.97 to 3.87), K = 1, N = 67	Ι	Maximum consecutive cocaine-negative urines: SMD 0.14 (-0.30 to 0.59), K = 1, N = 79	Cocaine Proportion negative urines: $SMD - 0.59 (-1.22 \text{ to } 0.05)$, $K = 1$, $N = 40$ Opioids Proportion negative urines: $SMD - 0.63 (-1.27 \text{ to } 0.01)$, $K = 1$, $N = 40$ Cocaine and opioids Negative urines during treatment: $RR 2.48 (1.40 \text{ to } 4.37)$, $K = 2$, $N = 170$ Proportion negative urines: $SMD - 0.66 (-1.30 \text{ to } -0.02)$, $K = 1$, $N = 40$
Point abstinence	I	Cocaine Endpoint: RR 0.96 (0.63 to 1.45), K = 1, N = 94 3-month follow-up: RR 1.04 (0.68 to 1.61), K = 1, N = 94	Cocaine (secondary to MMT) Endpoint: RR 0.94 (0.74 to 1.19), K = 1, N = 291 6-month follow-up: RR 1.01 (0.72 to 1.41), K = 1, N = 291	Cocaine Endpoint: RR 0.60 (0.25 to 1.43), K = 1, N = 56 Opioids Endpoint: RR 0.82 (0.51 to 1.32), K = 1, N = 56

			Opioids	
			Endpoint: RR 1.05	
			(0.83 to 1.32),	
			K = 1, N = 291	
			6-month follow-up:	
			RR 0.89 (0.65 to 1.23),	
			K = 1, N = 291	
			Cocaine and opioids	
			Endpoint: RR 0.99 (0.73	
			to 1.34), $K = 1$, $N = 291$	
			6-month follow-up:	
			o-monu tonow-up.	
			RR 0.90 (0.59 to 1.36),	
			K = 1, N = 291	
Drug use	Cocaine	ı	ı	ı
	Self-reported days:			
	Change from baseline:			
	SMD 0.25			
	(-2.38 to 2.88),			
	K = 2, N = 219			

8.9.2 Definition of interventions

Pre-vocational training – Any approach to vocational rehabilitation in which participants are expected to undergo a period of preparation before being encouraged to seek competitive employment. This preparation could involve either work in a sheltered environment (such as a workshop or work unit), or some form of pre-employment training or transitional employment (Crowther, *et al.*, 2001).

Supported employment – Any approach to vocational rehabilitation that attempts to place service users immediately in competitive employment. It is acceptable for supported employment to begin with a short period of preparation, but this has to be of less than one month's duration and not involve work placement in a sheltered setting, or training, or transitional employment (Crowther *et al.* 2001).

8.9.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 57.

Table 57: Databases searched and inclusion/exclusion criteria for effectiveness of vocational interventions

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to September 2006; table of contents September 2006 to November 2006
Study design	RCT
Patient population	Adults and young people (see 4.5.2 for further details on definition of young people) who misuse cannabis, stimulants, opioids, polydrug misuse
Interventions	Pre-vocational training, supported employment, enhanced vocational interventions
Outcomes	Employment, abstinence, drug use

8.9.4 Studies considered¹⁵

The review team conducted a new systematic search for RCTs that assessed the efficacy and/or safety of pre-vocational training, supported employment and enhanced vocational interventions.

¹⁵Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

For pre-vocational interventions two trials (HALL1977; ZANIS2001) met the eligibility criteria, providing data on 150 participants. Both trials were published in peer-reviewed journals.

For supported employment, no trials met the eligibility criteria.

In addition, six trials were excluded from the analysis. The most common reason for exclusion was that the intervention was not likely to be applicable to UK drug treatment services (further information about both included and excluded studies can be found in Appendix 14).

8.9.5 Vocational interventions

Study information and a summary of the evidence for included trials is provided in Table 58. For further details on forest plots and full evidence profiles see appendix 15 and 16.

Table 58: Study information and evidence summary table for vocational interventions

	Pre-vocational interventions versus standard care
Total no. of trials (total no. of participants)	2 RCTs (N = 150)
Study ID	HALL1977 ZANIS2001
Problem drug or diagnosis	Opioid dependence (MMT)
Treatment length and duration	2 weeks, 26 hours: HALL1977 12 weeks, 12 hours: ZANIS2001
Length of follow-up	3 to 6 months
Age (years)	31 to 43
Evidence profile table number (Appendix 16)	Table A16-34
Overall quality of evidence	Moderate
Employment	Placed in a job for at least 1 day (at follow-up): RR 1.89 (1.24 to 2.89), K = 2, N = 150
Abstinence	_
Drug use	_

8.9.6 Clinical summary

There was a lack of studies assessing vocational interventions for people who misuse drugs. The two included trials found some positive data suggesting pre-vocational training may improve the likelihood of being placed in a job for at least 1 day. Further research is required to replicate these findings and would benefit from more long-term employment outcomes.

8.10 PSYCHOLOGICAL INTERVENTIONS FOR CARERS

8.10.1 Introduction

There is an increasing recognition that drug misuse affects the entire family and the communities in which these families live. For example, the Home Office's updated Drug Strategy (Home Office, 2002) includes targets on increasing access to help, advice and counselling for parents, carers and families of people who misuse drugs. Additionally, the NTA user satisfaction survey found that 25% of respondents felt that staff did not offer families and carers enough support (Best *et al.*, 2006). Therefore there is a need to assess whether interventions for carers are effective.

8.10.2 Definitions of interventions

5-Step intervention

The 5-Step intervention seeks to help families and carers in their own right, independent of relatives who misuse drugs. It focuses on three key areas: stress experienced by relatives, their coping responses and the social support available to them. Step 1 consists of listening and reassuring the carer, Step 2 involves providing relevant information, Step 3 counselling about coping, Step 4 counselling about social support and Step 5 discussion of the need for other sources of specialist help. This intervention consists of up to five sessions.

Community reinforcement and family training

Community reinforcement and family training is a manualised treatment programme that includes training in domestic violence precautions, motivational strategies, positive reinforcement training for carers and their significant other, and communication training. However, the primary aim of the treatment appears to be encouraging the person who misuses drugs to enter treatment. This intervention consists of up to five sessions.

Self-help support groups

A group of families and carers of people who misuse drugs meets regularly to provide help and support for one another.

Guided self-help

A professional offers a self-help manual (for example, based on the 5-Step intervention), provides a brief introduction to the main sections of the manual and encourages the families and/or carers of people who misuse drugs to work through it in their own time at home.

8.10.3 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline is in Table 59.

The review team conducted a new systematic search for RCTs that assessed the efficacy and/or safety of community reinforcement and family training and 5-step for families/carers of people who misuse drugs (see Table 59).

For community reinforcement and family training, two trials (Kirby *et al.*, 1999; Meyers *et al.*, 2002) met the eligibility criteria, providing data on 152 participants. Both trials were published in peer-reviewed journals.

For the 5-Step intervention, one trial (Copello *et al.*, 2007) met the eligibility criteria, providing data on 114 participants. This trial is in press.

In addition, two trials were excluded from the analysis because they did not have control groups.

Table 59: Databases searched and inclusion/exclusion criteria for clinical effectiveness of psychological interventions for carers

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to September 2006; table of contents September 2006 to November 2006
Study design	RCT
Patient population	Families and/or carers of people who misuse drugs
Interventions	Psychosocial interventions: community reinforcement and family training, 5-step
Outcomes	Reduced stress Increased coping

8.10.4 Community reinforcement and family training

In both trials (Kirby *et al.*, 1999; Meyers *et al.*, 2002), community reinforcement and family training was compared with 12-step-based self-help groups (including 12-step facilitation) for carers.

The primary outcomes of these studies were to encourage people who misuse drugs and who had refused treatment into treatment, to reduce carers' reported problems (social/emotional, relationship and health-related) and improve their psychological functioning (mood and social adjustment). Neither study found statistically significant differences between community reinforcement and family training and 12-step-based self-help groups in relation to carer problems and psychological functioning. Kirby and colleagues (1999) found statistically significant changes from baseline for both groups in relation to carer problems and psychological functioning. However, Meyers and colleagues (2002) found no statistically significant differences (after Bonferroni corrections for multiple testing) in changes from baseline at 12-month follow-up.

8.10.5 5-step intervention

Copello and colleagues (2007) conducted a cluster-randomised trial (number of clusters = 137, number of participants = 143) comparing two intensities of a 5-step intervention. Primary care professionals were trained how to offer the 5-step intervention and asked to recruit and deliver the intervention to family members of people who misuse drugs and/or alcohol. All family members had experienced significant distress and lived with the person who misuses drugs or alcohol in the last 6 months. The majority of the sample were relatives of people who misuse alcohol; only 41.2% were relatives of people who misuse drugs. The largest proportions of family members included in the study were wives (43.1%) and children (35.3%).

Each primary care professional was treated as a cluster and was randomised to either the full intervention or guided self-help condition. The 'full intervention' consisted of up to five sessions, while guided self-help comprised one session where the primary care professional introduced the self-help manual (based on the 5-step model used in the full intervention) to the family member and encouraged him or her to work through it in his or her own time.

The two primary outcomes related to physical and psychological health (symptom rating test) and coping (the coping questionnaire). No statistically significant differences were found between the full intervention and the guided self-help conditions for both physical and psychological health (WMD = 0.23; 95% CI, -4.11 to 3.65) and coping (WMD = 0.12; 95% CI, -5.42 to 5.19).

8.10.6 Clinical summary

For both community reinforcement and family training and 5-step intervention, there were no statistically significant differences found between these more intensive interventions and self-help (that is, 12-step self-help groups and guided self-help). It appears that self-help interventions are as effective as more intensive psychological interventions in reducing stress and improving psychological functioning for carers and families of people who misuse drugs.

8.10.7 Clinical practice recommendations

- 8.10.7.1 Where the needs of families and carers of people who misuse drugs have been identified, staff should:
 - offer guided self-help, typically consisting of a single session with the provision of written material
 - provide information about, and facilitate contact with, support groups, such as self-help groups specifically focused on addressing families' and carers' needs.
- 8.10.7.2 Where the families of people who misuse drugs have not benefited, or are not likely to benefit, from guided self-help and/or support groups and continue to have significant problems, staff should consider offering individual family meetings. These should:
 - provide information and education about drug misuse
 - help to identify sources of stress related to drug misuse
 - explore and promote effective coping behaviours
 - normally consist of at least five weekly sessions.

9. RESIDENTIAL, PRISON AND INPATIENT CARE

9.1 INTRODUCTION

This chapter considers the extent to which the setting in which drug treatment is provided can have an impact upon the effectiveness of that treatment. Drug treatment in the UK currently takes place in a variety of settings, which are considered in the tiered approach to treatment (NTA, 2006a). In this system, tier 1 treatment refers to the provision of generic services to people who misuse drugs (for example, provision of general medical services by GPs). Tier 2 treatment refers to low-threshold drug-specific services such as needle and syringe distribution. Tier 3 treatment refers to more structured interventions for drug misuse, which are delivered in the community; examples of such interventions include opioid maintenance therapy and drug-misuse-specific psychological therapies. Tier 4 treatment refers to structured interventions that take place in residential settings; examples include drug treatment in residential rehabilitation centres, prisons or hospitals. The primary focus of this chapter is tier 4 services, but where possible comparisons will be made with services provided at other tiers.

In the UK, most structured drug treatment takes place in the community provided by statutory and independent sector services. Traditionally this has been through people who misuse drugs volunteering to enter treatment. However, there has recently been a rapid expansion in forms of so-called 'coerced' treatment. Coerced treatment, also referred to as legally mandated treatment, requires that the person who misuses drugs enter into treatment as an alternative or adjunct to criminal sanctions (Wild *et al.*, 2002). Such treatment can either be legally ordered by the court or through diversion away from the judicial process, usually following arrest and charge of the person who misuses drugs for drug-related and other offences.

Despite the recent policy shift to diversion away from the courts, however, many people who misuse drugs still serve prison sentences. Strang and colleagues (2006) found that 55% of a random sample of male prisoners in England and Wales had reported prior use of heroin, cocaine or amphetamine and that 59% of these prisoners had reported using these drugs a month before current imprisonment. Furthermore, over recent years, the prison population in the UK has been rising, suggesting the importance of drug misuse treatment in the prison setting. Such treatment is increasingly being offered following a number of recent developments, including the phased transfer of responsibilities for commissioning healthcare in publicly funded prisons from the Home Office to the NHS (DH, 2006a). While the mainstay of treatment has traditionally been detoxification upon admission to prison, there has been a recent policy change allowing increased access to opioid substitution therapy and psychosocial interventions.

Despite the increasing recognition and availability of appropriate specialist treatment in hospitals, the primary method of planned alternative treatment to community services remains residential rehabilitation. Best and colleagues (2005) estimated that 6,090 places were made available for residential rehabilitation in 2003/4. Day and colleagues (2005) also conducted a survey, although the focus was predominantly on provision of inpatient detoxification. There were an estimated 532 beds available for people who misuse drugs in residential rehabilitation units in the UK, with a total of 1,085 admissions per year. In contrast, there were estimated to be 356 specialist inpatient beds available for people who misuse drugs, with an estimated 6,829 annual admissions. In addition, there were an estimated 103 beds available in non-specialist psychiatric or medical wards, with a total of 2,077 admissions per year. This resulted in a combined estimate of 10,711 annual admissions for people who misuse drugs in inpatient or residential treatment (Day *et al.*, 2005).

9.2 INPATIENT SETTINGS

The key feature of an NHS inpatient unit for the treatment of drug misuse is the provision of assessment, stabilisation and/or detoxification, and psychosocial interventions with 24-hour cover from a multidisciplinary team (including psychiatrists, psychologists, nurses, occupational therapists, and so on) with specialist training in drug misuse. Inpatient treatment is provided for people with significant physical or psychiatric comorbidities who require 24-hour medical care (Specialist Clinical Addiction Network [SCAN], 2006).

Day and colleagues' (2005) survey of inpatient services in England found that NHS inpatient units offered a mean of 18 hours per week of psychological treatment predominantly delivered within groups. The most frequently provided psychological treatments in this setting were relapse-prevention CBT (82%), motivational enhancement (50%) and standard CBT (43%).

The primary drug problems for most people admitted to inpatient units were opioid misuse (35%), polydrug misuse (12%), and drug and alcohol misuse (10%). In contrast, only 3% of people admitted had a primary stimulant problem (Day $et\ al.$, 2005).

There are no studies that have specifically assessed the efficacy of inpatient treatment in comparison with a meaningful control group. Although NTORS included eight NHS inpatient units, outcomes from residential and inpatient settings were combined; therefore specific conclusions on the efficacy of inpatient treatment are not possible (Gossop *et al.*, 2003).

9.2.1 Clinical practice recommendation

9.2.1.1 The same range of psychosocial interventions should be available in inpatient and residential settings as in community settings. These should normally include contingency management, behavioural couples therapy

and cognitive behavioural therapy. Services should encourage and facilitate participation in self-help groups.

9.3 RESIDENTIAL SETTINGS

9.3.1 Introduction

It has been accepted policy for some time that residential rehabilitation centres comprise an important element in the integrated care pathways for people who misuse drugs at different stages of their treatment, and are of particular importance in providing a possible pathway out of dependence (NTA, 2006b). However, residential rehabilitation treatment has not experienced the same growth as community-based treatment options, and some have argued for the need to increase both its availability and uptake (for example, Best *et al.*, 2005). The absence of good evidence from formal evaluations of the relative efficacy of residential centres compared with community-based alternatives may be one reason for this limited expansion in services. In addition little is known about which subgroups of the drug misusing population are most likely to benefit from treatment in residential settings, the relative treatment and cost effectiveness of different types of treatment philosophy, and the cost-effective length of stay in such units.

In recent years the primary focus of drug misuse treatment in the UK has tended towards harm reduction rather than abstinence. However, recent policy changes have brought a renewed focus on abstinence as a primary treatment goal (NTA, 2005) and, in line with this shift in attitude, there has been a growing number of residential facilities in the UK offering abstinence-oriented treatment. Many residential rehabilitation programmes aim to achieve abstinence from substance misuse, and offer psychosocial support and provide structured programmes of daily activities, which residents are required to attend. In England, the NTORS (Gossop *et al.*, 1999) has identified 12-step programmes and therapeutic communities along with Christian houses as the main providers of residential services. Although it should be noted that in practice many residential rehabilitation programmes may be labelled '12-step' or a 'therapeutic community', a substantial number of residential rehabilitation programmes are often eclectic in nature drawing on a variety of approaches.

12-step-based residential treatment

Just under half of the services in the NTA online directory of residential rehabilitation centres currently describe themselves as 12-step-based (Meier, 2005). The 12-step model, an increasingly broad term stemming from the 12 steps of the AA model, assumes that people who misuse drugs have lost control over their dependence as a result of biological or psychological vulnerability (Alcoholics Anonymous, 2006). Treatment attempts to bring about recognising the condition by admitting to having an 'addict' identity, and accepting abstinence as the goal of treatment by involvement in 12-step activities (Finney *et al.*, 1998). In the context of residential treatment, residents usually work their way through the steps as part of a planned programme of

care, which also involves other individual and group therapeutic activities. The residential element of 12-step programmes is often quite short, lasting no longer than 3 months, but ex-residents will be expected to continue to attend self-help group meetings in the community, for example NA and CA (NTA, 2006b).

Therapeutic communities

Over half of residential services in the NTA online directory describe themselves as therapeutic communities, which, like 12-step programmes, have abstinence from illicit and prescribed drugs as a primary goal. Where they differ from other treatment approaches is in the use of the residential 'community' as the key agent for change. Peer influence is used to help individuals acquire social skills and learn social norms, and so take on an increased level of personal and social responsibility within the unit (Smith *et al.*, 2006). In addition to social learning theory based therapeutic communities, there are rehabilitation centres that emphasise more behavioural, hierarchical principles that positively and negatively reinforce a range of behaviours. Residential therapeutic communities involve therapeutic group work, one-to-one keyworking, the development of practical skills and interests, education and training. The intensive nature of their approach means that such programmes tend to be longer in duration (6 to 12 months) (Greenwood *et al.*, 2001). In the UK, Community of Communities (Keenan & Paget, 2006) has developed standards of good practice for therapeutic communities.

The evidence base for residential units

There have been a number of cohort studies in the UK, US and Australia that have investigated residential treatment. Many of these have reported improved outcomes (Bennett & Rigby, 1991; De Leon & Jainchill, 1982; Gossop *et al.*, 1999). NTORS included 15 residential rehabilitation units and found that about half of the service users (51%) had been abstinent from opioids throughout the 3 months prior to 1-year follow-up; rates of injection drug use were also halved, and rates of needle sharing were reduced to less than a third of intake levels (Gossop *et al.*, 1999).

The NTORS 4- to 5-year follow-up found that the percentage of residential service users who were abstinent from illicit drug use had increased from 1% at intake to 38% after 4–5 years. Almost half (49%) of the residential service users were abstinent from heroin after the same period (Gossop *et al.*, 2003). In the Drug Abuse Reporting Programme (DARP), Simpson and Sells (1990) found that most of the long-term (12 years) improvement was attained in the first 3 years after treatment. The similarities between the results of the NTORS and those of studies such as the DARP, Treatment Outcome Prospective Study (TOPS) and Drug Abuse Treatment Outcome Study (DATOS) (Hubbard *et al.*, 1989; Simpson & Sells, 1990; Hubbard *et al.*, 1997) have been noted (for example, Leshner, 1997).

The US DATOS examined predictors of self-reported health status among a sample comprising 10,010 service users receiving treatment for drug misuse. Results revealed that there were good outcomes after 1 year for service users (n = 2,966) treated using long-term residential and short-term inpatient treatment modalities. Regular cocaine misuse, the most common presenting problem, was reduced to about

one third of intake levels among service users from both the long- and short-term programmes, as was regular heroin misuse (Flynn *et al.*, 1997). Rates of abstinence from cocaine and heroin also improved after residential treatment.

Although these large-scale cohort studies provide some interesting data, there are a number of factors that limit their usefulness in evaluating residential treatment. Firstly, in the cohort studies discussed above, there is a lack of meaningful comparison groups. Therefore, conclusions are limited to before and after changes in outcome for the residential treatment group, with the possibility that changes may be due to spontaneous recovery or some systematic bias in the selection of those who enter residential treatment. Additionally, data from very different residential treatments are often combined, therefore making it impossible to assess the effectiveness of various types of residential treatment. These limitations suggest the need for studies that use appropriate comparison groups and assess the efficacy of specific types of residential treatment.

9.3.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 60.

Table 60: Databases searched and inclusion/exclusion criteria for clinical effectiveness of residential treatment

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT and cohort
Patient population	People who misuse drugs
Interventions	Residential interventions
Outcomes	Abstinence, drug misuse

9.3.3 Studies considered¹⁶

The review team conducted a new systematic search for RCTs and cohort studies that assessed the efficacy of residential interventions. Comparisons between residential

¹⁶Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

and community-based treatment, as well as meaningful comparisons between residential treatments, were focused on.

For the review of therapeutic communities, two RCTs (GREENWOOD2001; NEMES1999) met the eligibility criteria set by the GDG, providing data on 673 participants. Both were published in peer-reviewed journals.

For the review of 12-step residential treatment, one cohort study (FINNEY1998) met the eligibility criteria set by the GDG, providing data on 3,018 participants. This was published in a peer-reviewed journal.

For the review comparing residential and day treatments, three RCTs (ALTER-MAN1993; GREENWOOD2001; SCHNEIDER1996) met the eligibility criteria set by the GDG, providing data on 429 participants. Both were published in peer-reviewed journals.

In addition, 15 studies were excluded from the analysis. The most common reason for exclusion was not providing required outcomes (further information about both included and excluded studies can be found in Appendix 14).

9.3.4 Outcomes

The primary outcomes assessed were related to abstinence and drug use. Abstinence can be expressed in a variety of ways, but the two main measures examined were point abstinence and duration of abstinence. Point abstinence refers to evidence for the absence of drug use at a particular point in time (for example, end of treatment or at 12-month follow-up). Measures of the duration of abstinence over a period of time were also assessed, for example, how long a person remained abstinent, and the proportion of days a person was abstinent over a period of time. Measures based on urinalysis were preferred but self-report measures were not excluded.

Frequency of illicit drug use was also an important measure because, although abstinence may be a desired goal, reducing drug misuse may be a more realistic way of reducing drug-related harm. Drug misuse is usually measured by self-report, often in terms of the frequency of using particular drugs over a period of time.

9.3.5 Therapeutic communities (TCs)

Table 61 summarises the data on therapeutic communities. No differences in abstinence at 12-month (RR = 0.90; 95% CI, 0.67 to 1.22) or 18-month follow-up (RR = 0.86; 95% CI, 0.65 to 1.14) were found between a residential therapeutic community and a day treatment therapeutic community programme (Greenwood *et al.*, 2001). Nemes and colleagues (1999) found that a 12-month course of treatment that included at least 6 months in a residential therapeutic community followed by community aftercare was as effective as 10 months in a residential therapeutic community followed by 2 months of community aftercare in terms of abstinence outcomes. However, the lack of an adequate comparison group (for example,

Table 61: Study information and summary evidence table for trials of therapeutic communities*

	Residential TC versus day treatment TC	10 months' residential +2 months' aftercare versus 6 months' residential +6 months' aftercare
Total no. of trials (total no. of participants)	1 RCT (N = 261)	1 RCT (N = 412)
Study ID	GREENWOOD2001	NEMES1999
Problem drug or diagnosis	Crack cocaine: 67% Heroin: 13% Alcohol: 10%	Crack cocaine – percentages not provided
Treatment length	12 months	See above
Length of follow-up	18 months	12 months
Age (years)	33	No data provided
Point abstinence	12-month follow-up: RR 0.90 (0.67 to 1.22), K = 1, N = 261	Abstinence from crack/ cocaine at 12-month follow-up: RR 1.10 (0.90 to 1.35), K = 1, N = 412
Duration of abstinence	_	_
Illicit drug use	_	_

^{*}Residential versus day treatment: RR > 1 favours residential.

10 months +2 months versus 6 months +6 months: RR > 1 favours 10 months +2 months.

community-based treatment or treatment as usual) makes it difficult to assess the efficacy of either treatment programme.

It is very difficult to draw conclusions from this data due to the sparseness of the evidence. Furthermore, it is questionable whether the high proportions of participants with a primary crack-cocaine problem reported in these studies are comparable with UK residential treatment populations, where only an estimated 3% had a primary stimulant problem (Day *et al.*, 2005). This evidence is consistent with Smith and colleagues (2006), who conducted a systematic review and concluded that there is a lack of research assessing the effectiveness of therapeutic communities or whether one type of therapeutic community is better than another.

9.3.6 12-step-based residential rehabilitation

Only one study was found assessing the effectiveness of 12-step-based residential treatment (see Table 62). This study was a large prospective cohort (n = 3,018) study that compared 12-step-based residential treatment with relapse-prevention CBT and eclectic (combining elements of 12-step and CBT approaches) residential treatments (FINNEY1998). At 12-month follow-up, participants receiving 12-step-based treatment were more likely to remain abstinent and had fewer substance use problems than those in the relapse-prevention CBT and eclectic programmes. However, for both comparisons the effect was small and would equate to a risk difference of 0.09 (95% CI, 0.05 to 0.13) and number needed to treat of 11 (95% CI, 7.69 to 20.00) for 12-steps compared with the relapse-prevention CBT group. For 12-steps compared with the eclectic group a risk difference of 0.05 (95% CI, 0.01 to 0.10) and a number needed to treat of 20 (95% CI, 10 to 100) was found.

Table 62: Study information and summary evidence table for trials of 12-step residential treatment*

	Residential 12-step versus residential relapse-prevention CBT	Residential 12-step versus eclectic residential
Total no. of trials (total no. of participants)	1 cohort study (N ~ 1,500)	1 cohort study (N ~ 1,500)
Study ID	FINNEY1998	FINNEY1998
Problem drug or diagnosis	Drug dependence (13%) Drug and alcohol dependence (51%) Alcohol dependence (36%)	Drug dependence (13%) Drug and alcohol dependence (51%) Alcohol dependence (36%)
Treatment length	3 to 4 weeks	3 to 4 weeks
Length of follow-up	12 months	12 months
Age (years)	43	43
Point abstinence	12-month follow-up: RR 1.25 (1.13 to 1.39), K = 1, N = 3,018	12-month follow-up: RR 1.13 (1.01 to 1.25), K = 1, N = 3,018
Drug use	_	_

^{*}RR > 1 favours 12-step.

9.3.7 Residential and day treatment

There were three trials comparing residential and day treatment (see Table 63).

Table 63: Study information and summary evidence table for trials comparing residential with day treatment*

	Residential treatment versus day treatment
Total no. of trials (total no. of participants)	3 RCTs (N = 429)
Study ID	ALTERMAN1993 GREENWOOD2001 SCHNEIDER1996
Problem drug or diagnosis	Cocaine dependence (100%): ALTERMAN1993 SCHNEIDER1996 Crack cocaine (67%): GREENWOOD2001 Heroin (13%): GREENWOOD2001 Alcohol (10%): GREENWOOD2001
Treatment length	ALTERMAN1993 Residential: 48 hours/week – group meetings that focus on overcoming denial and helping participants learn to cope with everyday problems and stresses Day treatment: 27 hours/week – group meetings that focus on overcoming denial and helping participants learn to cope with everyday problems and stresses GREENWOOD2001 Residential TC: 40 hours/week plus additional time at weekend for 12 months Day treatment TC: received in the same treatment centre with the same intensity but did not have the 24-hour structure of the programme SCHNEIDER1996 Residential: 30–42 hours/week for 2 weeks – group psychoeducation, relapse-prevention CBT, 12-step facilitation

Continued

Table 63: (Continued)

	Residential treatment versus day treatment
	Day treatment: 25 hours/week for 2 weeks – group psychoeducation, counselling, relapse-prevention CBT, 12-step facilitation
Length of follow-up	3 months: S CHNEIDER1996 4 months and 7 months: ALTERMAN1993 7 months, 12 months to 5 years: GREENWOOD2001
Age (years)	31 to 40
Evidence profile table number (Appendix 16)	Table A16-35
Overall quality of evidence	Low
Point abstinence	Abstinence for TC at 12-month follow-up: RR 0.90 (0.67 to 1.22), K = 1, N = 261 Abstinence at 3-4 month follow-up: RR 1.14 (0.57 to 2.28), K = 2, N = 168 Abstinence at 6-7 month follow up: RR 1.07 (0.75 to 1.51), K = 2, N = 355
Drug use	_

^{*}RR > 1 favours residential.

One trial compared therapeutic communities in residential and day treatment (GREENWOOD2001). All participants received their treatment in the same treatment centre; the first 6 months of treatment was focused on drug misuse problems and the last 6 months helped participants develop independent employment and living arrangements. The main differences between the groups were that the day treatment group did not have the 24-hour structure experienced by the residential group. Additionally, the requirement of abstinence from illicit drugs was more stringent for the residential group, who were immediately expelled from the programme for noncompliance. Although abstinence was also a requirement for the day treatment group, this was enforced more flexibly.

Two trials compared eclectic residential and day treatment. One intervention was for 2 weeks (SCHNEIDER1996) and the other for 4 (ALTERMAN1993). For both trials the residential group was more intensive than the day treatment group (see Table 63).

At follow-up periods of up to 12 months, no differences were found between residential and day treatment groups, although there was some heterogeneity for 3- to 4-month and 6- to 7-month follow-ups. At follow-up, one study (ALTERMAN1993)

marginally favoured day treatment, whereas the others marginally favoured residential treatment at 3-month (SCHNEIDER1996) and 6-month follow-up (GREENWOOD2001). Despite some heterogeneity, the overall conclusion of all three trials is that there is little difference between outcomes in residential and day treatment groups.

9.3.8 Predictors of benefit from residential rehabilitation

The DATOS, conducted in the US, found that service users with a history of previous residential treatment engagement had poorer outcomes (Anglin *et al.*, 1997; Hser *et al.*, 1999), in contrast with clinical practice in the UK, where residential rehabilitation has traditionally been reserved for those who have tried and failed all other community- based options (Day *et al.*, 2005). There is some limited evidence to suggest that people with more severe problems will experience better outcomes from treatment stays of 90 days or longer, rather than programmes of shorter duration (Simpson, 1997). The NTORS found that for cocaine users improvements in rates of abstinence were found only among those in residential rehabilitation (Gossop *et al.*, 2003). However, the importance of this finding is difficult to interpret as cocaine misuse did not appear to be the primary problem for most participants in this study.

One issue that affects most research evaluations of residential rehabilitation programmes is that treatment dropout is common. As is the case with outcomes from other treatment modalities, service users who completed residential programmes achieved better outcomes on drug misuse, crime, employment and other social-functioning measures (De Leon & Jainchill, 1982; Hubbard *et al.*, 1989). It is unclear whether this relates to choice or motivation on the part of the service user or whether active retention in treatment achieves successful outcomes.

9.3.9 Clinical summary

There is a lack of well-conducted studies assessing the efficacy of residential in comparison with community-based treatment for drug misuse and the efficacy of specific types of residential treatment. Additionally, many studies (for example, Finney *et al.*, 1998) contain samples that have large proportions of participants who do not misuse drugs. Therefore, it is difficult to draw any firm conclusions from the studies on the comparative efficacy of 12-step-based and therapeutic community residential treatments or even whether these interventions confer any advantages over well-delivered community-based interventions. Given the relatively high costs of these interventions it is clear that further research in this area is urgently needed. There is some indication of benefit from cohort studies but in the absence of RCT evidence few conclusions can be drawn from them. It is also not possible to distinguish the additional benefit that might accrue to an individual from a period in residential rehabilitation over and above that obtained from the initial period of detoxification.

While traditional practice in the UK has been for service users to be referred for residential treatment when they have failed a long period of community care, there is some evidence to suggest that those less well established in their drug using careers may benefit from residential care.

9.3.10 Clinical practice recommendations

- 9.3.10.1 Residential treatment may be considered for people who are seeking abstinence and who have significant comorbid physical, mental health or social (for example, housing) problems. The person should have completed a residential or inpatient detoxification programme and have not benefited from previous community-based psychosocial treatment.
- 9.3.10.2 People who have relapsed to opioid use during or after treatment in an inpatient or residential setting should be offered an urgent assessment. Offering prompt access to alternative community, residential or inpatient support, including maintenance treatment, should be considered.

9.3.11 Research recommendation – residential treatment

9.3.11.1 Is residential treatment associated with higher rates of abstinence or reduction in drug misuse than community-based care?

Why this is important

There have been some studies comparing residential treatment with community-based treatment. However, these studies are often based on small sample sizes, lack methodological quality and have produced inconsistent results. Residential treatment requires significantly more resources than community-based treatment, so it is important to assess whether residential treatment is more effective.

9.4 LEGALLY COERCED TREATMENT INTERVENTIONS

9.4.1 Introduction

Recently in the UK, drug treatment has increasingly been legally coerced either by order or a court, or by diversion from the judicial system. Commentators have noted that compulsory (also known as legally coerced) treatment is perceived in a variety of ways. For example, Wild and colleagues (2002) found that evaluations of those receiving compulsory treatment have shown wide variations in perceptions of coercion, readiness to change their behaviour and the perceived justifiability of compulsory treatment to socially control their drug misuse. Additionally, although compulsory treatment status does predict a perceived level of coercion, many individuals do not

feel forced into treatment. Paradoxically, many who self-refer do report feeling coercion, often by family members (Polcin & Weisner, 1999).

The critical question for NHS services is whether people who misuse drugs who are engaged in criminal activity require criminal sanctions, drug treatment or a combination of both. This section presents the evidence pertaining to the effectiveness of coerced versus voluntary treatment across a number of outcome variables. These outcomes include uptake of treatment, retention in treatment, abstinence from drugs or a reduction in drug taking, and reduction in rates of imprisonment.

9.4.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline are in Table 64.

For the review of legally mandated treatment, one systematic review (Wild *et al.*, 2002) met the eligibility criteria set by the GDG. This review was published in a peer-reviewed journal.

Table 64: Databases searched and inclusion/exclusion criteria for clinical effectiveness of legally coerced treatment

Electronic databases	MEDLINE, EMBASE, CINAHL, HMIC, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT Observational studies Systemic reviews
Patient population	People who misuse drugs
Interventions	Legally coerced drug treatment
Outcomes	Abstinence, drug misuse

9.4.3 Comparisons of legally coerced and voluntary treatment

Most of the research in this area has been conducted in the US. Wild and colleagues' (2002) systematic review showed that compulsory treatment generally demonstrated better outcomes in terms of treatment process; that is, uptake of treatment following referral and retention in treatment. However, compulsory treatment was not superior to voluntary treatment in terms of reductions in criminal behaviour or substance misuse.

A 12-month prospective cohort study in Australia of 92 heroin users compared those receiving compulsory treatment with those who self-referred. They found that cumulative incarceration rates were higher in the coerced group than the voluntary treatment group, and that the coerced group was more problematic (that is, had lower levels of education and employment and higher levels of antisocial behaviour) at baseline (Desland & Batey, 1992).

A US-based study of 610 service users compared those legally coerced to methadone maintenance treatment with those who accessed MMT voluntarily. They found a higher dropout rate, due to incarceration, for those legally coerced to treatment. However, there was no difference between the groups at 1-year follow-up for percentage of positive urine samples (Desmond & Maddux, 1996).

9.4.4 Clinical summary

There is limited research assessing the efficacy of legally coerced treatment. Despite the potential concerns of some commentators, the evidence reviewed above does suggest that the more negative outcomes found in compulsory treatments may be explained by the nature of the difficulties of those entering coerced treatment when compared with those in voluntary treatment, rather than the compulsory nature of the treatment.

9.4.5 Clinical practice recommendation

9.4.5.1 For people who misuse drugs, access to and choice of treatment should be the same whether they participate in treatment voluntarily or are legally required to do so.

9.5 PRISON

9.5.1 Introduction

Relatively few studies have evaluated the effectiveness of prison-based psychosocial interventions. In this section, research findings are presented for the effectiveness of the following interventions based in the prison setting:

• Therapeutic communities, which use the residential 'community' as the key agent for change. Peer influence is used to help individuals acquire social skills and learn social norms and so take on an increased level of personal and social responsibility within the unit (Smith *et al.*, 2006). Therapeutic communities involve therapeutic group work, one-to-one keyworking, the development of practical skills and interests, education and training. The intensive nature of their approach means that such programmes tend to be relatively long in duration (6–12 months) (Greenwood *et al.*, 2001).

- Therapeutic community work-release programmes, which are for people who
 have been released from prison and who misuse drugs. They consist of residential
 therapeutic community programmes with additional emphasis on assisting former
 prisoners to enter employment.
- Boot camps, which refer to the delivery of a correctional intervention within a paramilitary style of working.

9.5.2 Databases searched and inclusion/exclusion criteria

Information about the databases searched and the inclusion/exclusion criteria used for this section of the guideline can be found in Table 65.

Table 65: Databases searched and inclusion/exclusion criteria for clinical effectiveness of prison-based psychosocial interventions

Electronic databases	MEDLINE, EMBASE, PsycINFO, Cochrane Library
Date searched	Database inception to May 2006; table of contents December 2005 to November 2006
Study design	RCT Observational studies
Patient population	People who misuse drugs
Interventions	Prison-based treatment: therapeutic communities, 12-steps Community-based post-release residential treatment: therapeutic communities, 12-steps Boot camps, shock incarceration
Outcomes	Abstinence, drug misuse, reincarceration, recidivism, criminal activity

9.5.3 Studies considered¹⁷

The review team conducted a new systematic search for RCTs and observational studies that assessed the efficacy of prison-based and post-release treatment.

For the prison-based and post-release therapeutic community review, three RCTs (NIELSEN1996; SACKS2004; WEXLER1999) met the eligibility criteria set by the GDG, providing data on 1,682 participants. All of these were published in peer-reviewed journals.

¹⁷Here, and elsewhere in the guideline, each study considered for review is referred to by a study ID in capital letters (primary author and date of study publication, except where a study is in press or only submitted for publication, then a date is not used).

For the review of boot-camps, two studies conducted by Zhang and colleagues (2000) met the eligibility criteria. These were published in a peer-reviewed journal.

In addition, 12 studies were excluded from the analysis. The most common reason for exclusion was unrequired outcomes (further information about both included and excluded studies can be found in Appendix 14).

9.5.4 Outcomes

Relapse is referred to here as the use of any illicit drugs during treatment or at follow-up.

Illicit drug use is the frequency of illicit drug use over a period of time and is usually measured by self-report.

Criminal activity is referred to here as the frequency of criminal activity committed by a person. This is often measured by self-report as not all criminal activity will be officially detected.

Recidivism is the frequency of a person being arrested and charged for criminal activity.

Reincarceration relates to whether a person who has been released from prison has returned to prison after a particular period of time.

9.5.5 Interventions in prison

Summary study information and evidence from the included trials are shown in Table 66. For further details on forest plots and full evidence profiles see Appendix 15 and 16.

Three RCTs have been conducted in the prison setting evaluating the evidence for psychosocial interventions. All of the three RCTs evaluated therapeutic communities and were conducted in the US (NIELSEN1996; SACKS2004; WEXLER1999). In two of the three trials the intervention included treatment within prison followed by release to a residential community of 6 months' duration (SACKS2004; WEXLER1999). The third trial (NIELSEN1996) assessed a work-release therapeutic community programme.

The main outcomes were for crime and relapse and were assessed over a follow-up period of up to 5 years. In summary, therapeutic community prison and aftercare programmes and therapeutic community work-release programmes were associated with reductions in criminal activity (RR = 0.69; 95% CI, 0.52 to 0.93), recidivism (RR = 0.65; 95% CI, 0.53 to 0.78) and relapse (RR = 0.49; 95% CI, 0.49 to 0.58). For reincarceration, the difference was not statistically significant at 12-month follow-up (RR = 0.48; 95% CI, 0.20 to 1.12) but there was a strong trend favouring prison therapeutic communities, with a number needed to treat of five. At 5-year follow-up the difference was statistically significant (RR = 0.93; 95% CI, 0.87 to 0.99).

In addition, there were two retrospective cohort studies on boot camps with a total of 854 participants reported by a team of researchers in the US (Zhang *et al.*, 2000).

Table 66: Study information and summary evidence table for trials of prison and work-release therapeutic communities, and boot camps*

	Prison TC + aftercare versus prison control	Residential TC work-release Boot camp ver programmes versus standard juvenile camp aftercare	Boot camp versus traditional juvenile camp
Total no. of trials (total no. of participants)	2 RCTs (N = 993)	1 RCT (N = 688)	Retrospective cohort study $(N = 854)$
Study ID	SACKS2004 WEXLER1999	NIELSEN1996	Zhang et al. (2000): Studies 1 and 2
Diagnosis	Drug: 20% crack/cocaine, 30% cannabis, 30% alcohol Psychiatric: 70% Axis I, 39% antisocial personality disorder (SACKS2004) Drug: 100% illicit drug use Psychiatric: 51.5% antisocial personality disorder (WEXLER1999)	Cocaine: 40% Crack: 11% Heroin: 13% Cannabis: 11% Alcohol: 13%	Drug and/or alcohol history
Treatment length	1 year prison TC and 1 year community-based aftercare: WEXLER1999 1 year prison TC and 6 months' community-based aftercare: WEXLER1999	6 months	6 months' boot camp and 6 months' aftercare

Length of follow-up	1 to 5 years	1 year	1 year
Evidence profile table number (Appendix 16)	Table A16–36	I	I
Overall quality of evidence	Moderate	I	I
Illicit drug use	1	Relapse 6-month follow-up: RR 0.49 (0.41 to 0.58), K = 1, N = 688	Illicit drug use 12-month follow-up: SMD -0.21 (-0.49 to 0.06), $K = 1$, $N = 200$
Crime	Reincarceration: 12-month follow-up: RR 0.48 (0.20 to 1.12), K = 2, N = 688 N = 854 5-year follow-up: RR 0.99 Criminal activity: RR 0.69 (0.52 to 0.93), K = 1, N = 139	Recidivism 6-month follow-up: RR 0.65 (0.53 to 0.78), K = 1, N = 688	Arrested 12-month follow-up: RR 0.95 (0.73 to 1.22), K = 1, N = 200 Arrested 4-year follow-up: RR 0.99 (0.94 to 1.05), K = 1, N = 854

*RR < 1 favours intervention; negative SMD values favour intervention.

Participants in boot camps did not differ from controls for drug use at 12-month follow-up (SMD = -0.21; 95% CI, -0.49 to 0.06) and for proportion arrested at 12 months (RR = 0.95; 95% CI, 0.73 to 1.22) and 4 years (RR = 0.99; 95% CI, 0.94 to 1.05).

9.5.6 Clinical summary

The therapeutic community approach in prison settings in the US appeared to be associated with a reduction in reincarceration rates, criminal activity and recidivism and these effects were maintained at follow-up. The evidence also suggests that, subsequent to release from prison, continuing community-based interventions such as therapeutic community attendance or involvement in community-based work programmes may be important in maintaining the benefits of the intervention. In contrast, boot camps do not appear to be effective for offenders who misuse drugs – no differences were reported on crime outcomes and drug misuse at follow-up.

9.5.7 Clinical practice recommendations

- 9.5.7.1 For people in prison who have drug misuse problems, treatment options should be comparable to those available in the community. Healthcare professionals should take into account additional considerations specific to the prison setting, which include:
 - the length of sentence or remand period, and the possibility of unplanned release
 - risks of self-harm, death or post-release overdose.
- 9.5.7.2 People in prison who have significant drug misuse problems may be considered for a therapeutic community developed for the specific purpose of treating drug misuse within the prison environment.
- 9.5.7.3 For people who have made an informed decision to remain abstinent after release from prison, residential treatment should be considered as part of an overall care plan.

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APPENDIX 1:

SCOPE FOR THE DEVELOPMENT OF THE CLINICAL GUIDELINE

Final version

28th September 2005

GUIDELINE TITLE

Drug misuse: psychosocial management of drug misusers in the community and in prison. 18

Short title

Drug misuse: psychosocial interventions.

BACKGROUND

The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Mental Health (NCCMH) to develop a clinical guideline on psychosocial management of drug misusers¹⁹ in the community and prison settings, for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see Appendix [to the scope] below). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

The Institute has simultaneously commissioned the NCCMH to develop a clinical guideline on opiate detoxification of people who misuse drugs in the community, hospital and prison settings for use in the NHS in England and Wales.

The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.

¹⁸The guideline title changed during the development process to *Drug Misuse: Psychosocial Interventions* ¹⁹The term 'drug misusers' has been replaced with 'people who misuse drugs' throughout the guideline, with the exception of the scope.

NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

CLINICAL NEED FOR THE GUIDELINE

The term opiate is used throughout this scope. Although this term normally implies substances containing natural opium, in this scope the term is used more broadly to include opioids (synthetic substances with similar properties).²⁰

It is estimated that there are between 250,000 and 500,000 problem drug users in the UK, of whom about 125,500 are in treatment in any year. There is a government target of ensuring 200,000 are in effective treatment in 2008. The majority of those requiring treatment are opiate dependent (and currently or previously using illicit heroin), although the use of other drugs such as stimulants (for example cocaine) is known to be increasing.

Severe opiate dependence is a disorder of multi-factorial aetiology, with multiple and varied perpetuating factors. It has a central feature of psychological reinforcement of repeated drug-taking behaviour and it also has a marked withdrawal syndrome. Disturbances of the brain reward pathways may be important underlying pathological mechanisms. For this reason, it is usually considered that a range of interventions may be required in addition to pharmacological treatments.

There may be associated problems of family, social and criminal justice difficulties, health problems including blood-borne viruses, and other drug and alcohol problems. Families themselves may be affected by the drug misuse and are often a major resource in resolving problems and supporting the family member through treatment.

For people with severe drug dependency and others with long-standing dependency, the disorder has characteristics as a long-term chronic relapsing disorder with periods of remission and relapse, so while abstinence may be one of a range of long-term goals of treatment, it is not always achieved. Even when abstinence is achieved, the benefits are not always maintained, and periods of relapse may still occur.

The societal costs of drug misuse have been estimated at many billions of pounds, with opiate dependence and use of other Class A drugs constituting the main cause of these costs.

Opiate substitution therapies (methadone and buprenorphine are most commonly used) allow the patient to replace street heroin with a longer-acting, less euphoriant and safer drug, while avoiding the withdrawal syndrome. Once stabilised, many patients remain on maintenance treatment, which brings improvements in illicit drug use, physical health, well-being, social stabilisation and reduced criminality and costs to society. Pharmacological treatments for stimulant and cannabis misuse are not well developed.

²⁰The term 'opiates' has been replaced with the generic term 'opioids' throughout the guideline, with the exception of the scope and where the term relates specifically to the subset of opioids that are naturally occurring or semi-synthetic derivatives of the opium poppy, including heroin.

Psychosocial interventions play an important part in the treatment of drug misusers. For opiate misusers they are often an important adjunct to pharmacological treatments and have been demonstrated to be effective. For stimulant misusers, psychosocial interventions are the mainstay of effective treatment interventions and there is an established evidence base. A similar, but less well-developed, evidence base also exists for psychosocial interventions for cannabis misusers.

People who misuse drugs in prison sometimes receive assistance with withdrawal symptoms and some receive a treatment programme in prison. Access to regular high levels of illicit drugs in prisons is limited, so most people with drug dependency lose tolerance and are at risk of overdose if – as commonly happens – they begin using again on release.

THE GUIDELINE

The guideline development process is described in detail in two publications, which are available from the NICE website (see 'Further information'). *The Guideline Development Process – an Overview for Stakeholders, the Public and the NHS (Second Edition)* (NICE, 2006) describes how organisations can become involved in the development of a guideline. *The Guidelines Manual* (NICE, 2006) provides advice on the technical aspects of guideline development.

This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health (see Appendix [to the scope] below).

The areas that will be addressed by the guideline are described in the following sections:

POPULATION

Groups that will be covered:

- adults and young people who misuse opiates
- adults and young people who misuse cannabis
- adults and young people who misuse stimulants (for example, cocaine or amphetamines)
- adults and young people who misuse more than one of the above.

Groups that will not be covered:

- Adults and young people with dual diagnoses, where the primary diagnosis and
 focus of intervention is not substance misuse but another mental disorder, for example depression, schizophrenia or other psychoses. Where appropriate, this guideline
 will refer to other NICE guidance for the treatment of other mental health disorders.
- Adults and young people who misuse alcohol, where the primary diagnosis and focus of intervention is alcohol misuse.
- Adults and young people who misuse prescription drugs, for example benzodiazepines.

- Adults and young people who misuse solvents (for example, aerosols and glue) or other street drugs (for example, LSD [lysergic acid diethylamide]).
- Adults and young people prescribed opiates and related drugs for therapeutic purposes unrelated to substance misuse.

HEALTHCARE SETTING

The guideline will be of relevance to the NHS and related organisations, including:

- prison services
- inpatient and specialist residential and community-based treatment settings. This is an NHS guideline. Although it will comment on the interface with other services such as those provided by social services, educational services and the voluntary sector, it will not provide specific recommendations directed solely to non-NHS services, except insofar as they are provided under contract to the NHS.

CLINICAL MANAGEMENT - AREAS THAT WILL BE COVERED

The guideline will cover the following areas of clinical practice and will do so in a way that is sensitive to the cultural, ethnic and religious backgrounds of people who misuse drugs/are drug dependent and their families and carers.

- The guideline will include advice on the appropriate use of individual and group structured psychosocial interventions including their type, modality, frequency and duration. The psychosocial interventions considered may include motivational interviewing, cognitive behavioural therapy, contingency management, brief reinforcement-based intensive outpatient therapy, cue exposure therapy, programmes for treatment drop-outs, enhanced outreach counselling programmes, vocational rehabilitation programmes, family- and couples-based interventions and other psychological interventions provided in the NHS.
- The guideline will include the appropriate use of combination individual and/or group structured psychosocial interventions with pharmacological treatments. The pharmacological treatments will include methadone, buprenorphine, naltrexone and other appropriate pharmacological therapies.
- When referring to pharmacological treatments, the guideline will, wherever possible, recommend use within their licensed indications. However, where the evidence clearly supports it, recommendations for use outside the licensed indications may be made in exceptional circumstances.
- The safety, side effects and other disbenefits of the interventions reviewed will be considered.
- The guideline will address, where relevant, the issues of relapse prevention and the minimisation of harm and drug-related deaths.
- The guideline will include guidance on risk management and suicide prevention, including appropriate assessment and aftercare.

- The guideline will address the integration of the interventions reviewed with a broad approach to the care and treatment of people who misuse drugs/are drug dependent and their families and carers.
- The guideline will consider the separate needs of families and carers as well as addressing the potential positive contribution of family and carers in the treatment and support of people who misuse drugs/ are drug dependent.
- The guideline will address the various needs for information of patients, families
 and carers, at different stages of their treatment and in different settings, including the role of self-help interventions and of support and self help groups.

CLINICAL MANAGEMENT - AREAS THAT WILL NOT BE COVERED

• The guideline will not consider diagnosis or primary prevention.

STATUS

Scope

This is the final draft of the scope following consultation, which will be reviewed by the Guidelines Review Panel and the Institute's Guidance Executive.

The guideline will incorporate the following NICE guidance, which is published or in development:

Methadone and Buprenorphine for the Treatment of Opiate Drug Misuse. NICE technology appraisal. (Publication expected March 2007.)²¹

Naltrexone to Prevent Relapse in Drug Misuse. NICE technology appraisal. (Publication expected March 2007.)²²

Drug Misuse: Opiate Detoxification of Drug Misuse. NICE clinical guideline. (Publication expected July 2007.)²³

Schizophrenia: Core Interventions in the Treatment and Management of Schizophrenia in Primary and Secondary Care. NICE clinical guideline no. 1 (2002).

Anxiety: Management of Anxiety (Panic Disorder, with or without Agoraphobia, and Generalised Anxiety Disorder) in Adults in Primary, Secondary and Community Care. NICE clinical guideline no. 22 (2004).

Depression: Management of Depression in Primary and Secondary Care. NICE clinical guideline no. 23 (2004).

²¹This technology appraisal has now been published with a different title; NICE (2006e) *Methadone and Buprenorphine for the Management of Opioid Dependence. Evaluation Report.* London: NICE.

²²This technology appraisal has now been published with a different title; National Institute for Health and Clinical Excellence (NICE) (2006a) *Naltrexone for the Management of Opioid Dependence. Evaluation Report.* London: NICE.

²³This guideline has now been published with a different title; NICE (2007) *Drug Misuse: Opioid Detoxification*. NICE clinical guideline no. 52. London: NICE.

Self-Harm: the Short-Term Physical and Psychological Management and Secondary Prevention of Self-Harm in Primary and Secondary Care. NICE clinical guideline no. 16 (2004).

GUIDELINE

The development of the guideline recommendations will begin in September 2005.

FURTHER INFORMATION

Information on the guideline development process is provided in:

- The Guideline Development Process an Overview for Stakeholders, the Public and the NHS (Second Edition) (NICE, 2006)
- *The Guidelines Manual* (NICE, 2006).

These booklets are available as PDF files from the NICE website (www.nice.org.uk). Information on the progress of the guideline will also be available from the website.

APPENDIX - REFERRAL FROM THE DEPARTMENT OF HEALTH

The Department of Health asked the Institute to prepare a guideline for the NHS in England and Wales on the psychosocial management of drug misusers in the community and prison settings.

The guidance will:

- by using the evidence base, examine the effectiveness and cost effectiveness of psychosocial interventions for the management of opiate, stimulant and cannabis misusers
- identify those groups of drug misusers who are most likely to benefit from psychosocial interventions
- identify the key components of the effectiveness of these treatments, within a wider package of pharmacological interventions, and the overall care provided for drug misusers.

APPENDIX 2:

DECLARATIONS OF INTEREST BY GUIDELINE DEVELOPMENT GROUP MEMBERS

With a range of practical experience relevant to drug misuse in the GDG, members were appointed because of their understanding and expertise in healthcare for people who misuse drugs and support for their families and carers, including: scientific issues; health research; the delivery and receipt of healthcare, along with the work of the healthcare industry; and the role of professional organisations and organisations for people who misuse drugs and their families and carers.

To minimise and manage any potential conflicts of interest, and to avoid any public concern that commercial or other financial interests have affected the work of the GDG and influenced guidance, members of the GDG must declare as a matter of public record any interests held by themselves or their families that fall under specified categories (see below). These categories include any relationships they have with the healthcare industries, professional organisations and organisations for people who misuse drugs and their families and carers.

Individuals invited to join the GDG were asked to declare their interests before being appointed. To allow the management of any potential conflicts of interest that might arise during the development of the guideline, GDG members were also asked to declare their interests at each GDG meeting throughout the guideline development process. The interests of all the members of the GDG are listed below, including interests declared prior to appointment and during the guideline development process.

CATEGORIES OF INTEREST

- Paid employment
- Personal interests related to drug misuse: payment in cash or kind and/or funding from the drug misuse-related healthcare industry, including consultancies, grants, fee-paid work and shareholdings or other beneficial interests.
- Personal interests not specifically related to drug misuse: any other payment and/or funding from the healthcare industry, including consultancies, grants and shareholdings or other beneficial interests.
- Non-personal interests: funding from the healthcare industry received by the GDG member's organisation or department, but where the GDG member has not personally received payment, including fellowships and other support provided by the healthcare industry.
- Personal non-monetary interests: these include, but are not limited to, clear opinions or public statements you have made about drug misuse, holding office in a professional organisation or advocacy group with a direct interest in drug misuse, other reputational risks relevant to drug misuse.

- **Personal family interests:** payments in cash or kind that were received by a member of your family.
- Other interests relating to drug misuse: funding from governmental or non-governmental organisations, charities, and so on, and/or ownership in a company that provides therapy or treatments likely to be covered in the guideline.

Declarations of interest	
Professor John Strang – Chair, G	Guideline Development Group
Employment	Professor of Psychiatry of Addictions; Director – National Addiction Centre, Institute of Psychiatry; Honorary Consultant Psychiatrist and Clinical Director of Addictions Division, South London and Maudsley NHS Foundation Trust
Personal interests related to drug misuse	Consultancies from GW Pharmaceuticals, Britannia Pharmaceuticals, Napp Pharmaceuticals (consultancy per diem), Reckitt Benckiser (consultancy per diem), Schering-Plough (consultancy per diem), Johnson and Johnson (consultancy per diem)
Personal interests not specifically related to drug misuse	None
Non-personal interests	Research project grants (work commissioned by healthcare industry) – GW Pharmaceuticals (staff employment), Reckitt and Benckiser (staff employment). Phoenix House funding for the Fountain HIV rehabilitation project and payment to NHS Trust for sessions from consultant colleague.
Personal non-monetary interests	Chair of the Department of Health working group preparing drug misuse 'Orange' clinical guidelines 1998/1999 and 2006/2007. Previously on the management committee of Turning Point, Chatterton Hey and Kaleidoscope. Also, previously management committee and listed director of Lifeline Project.

Continued

Declaration	as of interest (Continued)
	Previously unpaid visiting psychiatrist at Phoenix House, also previously on national management committee and one of the Directors of Phoenix House nationally.
Personal family interests	None
Other interests related to drug misuse	Research grant from Action on Addiction for randomised trial of injectable opioid maintenance treatment (RIOTT).
	Project grant from the NTA for the 'take-home naloxone' project.
Dr Eliot Ross Albert	
Employment	None
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	Director of UK Harm Reduction Association; Trustee of National Users' Network
Personal family interests	None
Other interests related to drug misuse	None
Ms Janet Brotchie	
Employment	Clinical Psychology Advisor, Quality Team, NTA; Lead Psychologist, Central and North West London Mental Health NHS Trust Substance Misuse Service
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None

Declarations of interest (Continued)		
Dr Alex Copello		
Employment	Clinical Director, Substance Misuse Services and Addictions Research and Development Programme Director, Birmingham and Solihull Mental Health NHS Trust; Senior Lecturer in Clinical Psychology, University of Birmingham	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	Grant funded projects: ROUTES – good practice working with families affected by drug use in the Pakistani and African-Caribbean communities (DH 2005–2007, £115,000). Involving family members project (Alcohol Education Research Council 2004–2006).	
Professor Colin Drummond		
Employment	Professor of Addiction Psychiatry, St George's Hospital Medical School, University of London; Honorary Consultant Psychiatrist, South West London and St George's NHS Trust	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	

Continued

Declaration	as of interest (Continued)	
Other interests related to drug misuse	Current grant funded projects: evaluation of brief intervention among Drug Intervention Programme clients with alcohol problems (Home Office 2005–2006, £40,000); SCAN travelling research fellowship/SCAN development project (DH 2004–2006, £430,000); evaluation of brief intervention among Drug Intervention Programme clients with alcohol problems (Home Office 2005–2006, £40,000).	
Mr Mark Gilman		
Employment	North West Regional Manager, NTA	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Mr Tim Leighton		
Employment	Head of Professional Education, Training and Research, Clouds; Director of Studies, University of Bath Foundation Degree and BSc (Hons) in Addictions Counselling	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	Member of Senior Management Group, Clouds (registered charity)	
Personal family interests	None	
Other interests related to drug misuse	None	

Declarations of interest (Continued)	
Mr Peter McDermott	
Employment	Non-executive director, NTA; Regional advocate for The Alliance
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	Schering-Plough funded an information leaflet distributed by The Alliance.
Personal non-monetary interests	Member of Board of Trustees, Lifeline Project; member of Board of Trustees, Project 8.
Personal family interests	None
Other interests related to drug misuse	None
Mr Andy Stopher	
Employment	Borough Services Assistant Director (Camden), Substance Misuse Services, Camden and Islington Mental Health and Social Care Trust
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None
Mr Ian Wardle	
Employment	Chief Executive, Lifeline Project, Manchester
Personal interests related to drug misuse	None

Continued

Declaration	as of interest (Continued)	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Mrs Tina Williams		
Employment	Chief Executive for The Bridge Project carer service and PANIC user service	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	Non-executive director, NTA	
Personal family interests	None	
Other interests related to drug misuse	None	
Dr Nat Wright		
Employment	Clinical Director for Substance Misuse, HMP Leeds, Leeds Primary Care Trust	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	Grant funded project: evaluating the effectiveness of methadone versus buprenorphine for detoxification from opiates in the prison setting (DH 2004 £147,000).	

NCCMH STAFF

Mr Stephen Pilling – Facilitator	, Guideline Development Group
Employment	Joint Director, NCCMH; Director, Centre for Outcomes, Research and Effectiveness, University College London; Consultant Clinical Psychologist and Deputy Head of Psychology Services, Camden and Islington Mental Health and Social Care Trust
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	Lecture for UK Psychiatric Pharmacy Group, October 2006, £300 including expenses. Lecture at Andrew Simms Centre, Leeds, December 2006, £300 including expenses.
Non-personal interests	Grants for production of clinical guidelines and evidence-related practice: British Psychological Society Clinical Effectiveness Programme with Professor P. Fonagy and Professor S. Michie supporting production of NICE guidelines and related policy implementation work (£5.4 million, 2001–2010). Health service research grants: NHS Service Development and Organisation Research and Development Programme developing evidence-based and acceptable stepped-care systems in mental healthcare, an operational research project with Professor D. Richards, Professor S. Gallivan, Dr S. Gilbody, Professor K. Lovell, Dr J. Cape, Dr P. Bower and Ms J. Leibowitz (£299,642, 2006–2009); NHS Service Development and Organisation Research and Development Programme – The 100 Ward Study: a National Survey of Psychiatric Inpatient Unit Morale with Dr S. Johnson, Professor P. Bebbington, Professor M. King, Professor S. Woods, Professor N. Wellman, Dr D. Osborn and Dr R. Arraya (£296,999, 2006–2009).
Personal non-monetary interests	None
Personal family interests	None

Other interests related to drug misuse	None
Ms Sarah Hopkins	
Employment	Project Manager, NCCMH
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None
Ms Rebecca King	
Employment	Project Manager, NCCMH (2005–2006)
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None
Mr Ryan Li	
Employment	Research Assistant, NCCMH
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None

Dr Ifigeneia Mavranezouli		
Employment	Senior Health Economist, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Dr Nicholas Meader		
Employment	Systematic Reviewer, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Ms Peny Retsa		
Employment	Health Economist, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	

Ms Poonam Sood		
Employment	Research Assistant, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Ms Sarah Stockton		
Employment	Information Scientist, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	
Dr Clare Taylor		
Employment	Editor, NCCMH	
Personal interests related to drug misuse	None	
Personal interests not specifically related to drug misuse	None	
Non-personal interests	None	
Personal non-monetary interests	None	
Personal family interests	None	
Other interests related to drug misuse	None	

Mr Loukas Xaplanteris	
Employment	Health Economist, NCCMH
Personal interests related to drug misuse	None
Personal interests not specifically related to drug misuse	None
Non-personal interests	None
Personal non-monetary interests	None
Personal family interests	None
Other interests related to drug misuse	None

APPENDIX 3:

STAKEHOLDERS WHO RESPONDED TO EARLY REQUESTS FOR EVIDENCE

College of Occupational Therapists

Community Health Sciences, Edinburgh University, and Muirhouse Medical Group

Darwin Centre for Young People

Derbyshire Mental Health Services NHS Trust

Pfizer Ltd

Royal College of Nursing

Royal College of Pathologists

Royal College of Physicians of Edinburgh

Royal College of Psychiatrists

Royal Pharmaceutical Society of Great Britain

Sheffield Teaching Hospitals NHS Foundation Trust

Specialist Clinical Addiction Network

APPENDIX 4:

STAKEHOLDERS AND EXPERTS WHO SUBMITTED COMMENTS IN RESPONSE TO THE CONSULTATION DRAFT OF THE GUIDELINE

Stakeholders

Alcohol and Drug Addiction Prevention and Treatment

Altrix Healthcare plc

Association of Family Therapy

Berkshire Healthcare NHS Trust

Brighton Oasis Project

British Association for Counselling and Psychotherapy

The British Psychological Society

CASPE Research

College of Occupational Therapists

Compass-Services to Tackle Problem Drug Use

Department of Health

Derbyshire Mental Health Trust

European Association for the Treatment of Addiction

Federation of Drug and Alcohol Professionals

Leeds North East Primary Care Trust

National Treatment Agency for Substance Misuse

Northwest London Hospitals NHS Trust

Outcome Consultancy

Phoenix Futures

Rehabilitation of Addicted Prisoners Trust

Royal College of Midwives

Royal College of Nursing

Royal College of Pathologists

St Andrew's Healthcare

Schering-Plough Ltd

South London and Maudsley Acute Trust

Specialist Clinical Addiction Network

Turning Point

Western Counselling

Experts

Amanda Baker Paul Crits-Christoph John Marsden Jim McCambridge Kenneth Silverman George Woody

APPENDIX 5:

RESEARCHERS CONTACTED TO REQUEST INFORMATION ABOUT UNPUBLISHED OR SOON-TO-BE PUBLISHED STUDIES

Amanda Baker Donald Calsyn Kathleen M. Carroll Michael Crawford Paul Crits-Christoph George DeLeon Michael Dennis Karen Downey William Fals-Stewart David Farabee Michael Gossop Edward Gottheil Anke Gross Joseph Guydish Stephen Higgins Martin Iguchi Hendree Jones Kimberly C. Kirby Thomas Kosten

Jim McCambridge

Susanne MacGregor

Jane McCusker

James McKay Jesse Milby William Miller Jo Neale Ashwin Patkar Nancy Petry Richard Rawson Damaris Rohsenow Grace Rowan-Szal Karen Saules Joy Schmitz Harvey Siegal Kenneth Silverman Natasha Slesnick Robert Stephens Maxine Stitzer Betty Tai Olivia Washington Stephen Weinstein Roger Weiss

George Woody

David Zanis

APPENDIX 6:

CLINICAL QUESTIONS

TIER 1: DRUG-RELATED INFORMATION AND ADVICE, SCREENING AND REFERRAL BY GENERIC SERVICES

1) Are there sensitive and specific methods for the identification of people who misuse drugs in health and social care settings where drug misuse is prevalent or where presentations are associated with drug misuse as an aetiological factor?

TIER 2: OPEN ACCESS, NON-CARE-PLANNED DRUG-SPECIFIC INTERVENTIONS

- 2) For people who misuse drugs, are there effective psychosocial components of drug agencies* associated with reduced injection risk behaviours, reduced incidence of blood-borne diseases and engagement in treatment? *including needle and syringe exchange programmes, drop-in centres and outreach services
- For people who misuse drugs, are brief interventions associated with engagement in treatment, reduction/abstinence in use of drug(s)?
 - 3.1) For people who misuse drugs, are interventions of a longer duration (for example, 12 weeks or more) compared with brief interventions associated with a reduction in the use of drug(s)/ abstinence and reduced risk of relapse at follow-up?

TIER 3: STRUCTURED, CARE-PLANNED DRUG TREATMENT

- 4) For people who misuse drugs, what structured psychosocial interventions are associated with a reduction in the use of drug(s)/abstinence and reduced risk of relapse at follow-up?
- 5) For people who misuse drugs, what structured psychosocial interventions in combination with pharmacological interventions are associated with a reduction in the use of drug(s)/abstinence and reduced risk of relapse at follow-up?

TIER 4: RESIDENTIAL SETTINGS

6) For people who misuse drugs, are residential settings associated with a reduction in use of drug(s)/abstinence and reduced risk of relapse at follow-up?

- 6.1) For people who misuse drugs, are there particular subgroups who are more likely to benefit from treatment in residential settings?
- 7) For people who misuse drugs, are coerced interventions in comparison with no treatment and/or prison associated with reduced risk of relapse at follow-up and reduced crime?

APPENDIX 7:

SEARCH STRATEGIES FOR THE IDENTIFICATION OF CLINICAL STUDIES

1. GENERAL SEARCH FILTERS

Drug misuse

a.	MEDLINE, EMBASE, PsycINFO, CINAHL – Ovid interface
1	Amphetamine-related disorders/
2	Cannabis addiction/ or Marijuana abuse/
2	Cocaine dependence/ or Cocaine-related disorders/
4	Heroin addiction/
5	exp Narcotic dependence/
6	Opiate addiction/ or exp Opioid-related disorders/
7	Drug abuse/ or Drug abuse pattern/ or Drug addiction/ or Drug misuse/ or
	Drug overdoses/ or Intravenous drug abuse/ or Substance abuse/ or
	Substance-related disorders/ or 'Substance use disorders'/
8	Drug dependence/ or Drug dependency/ or Substance dependence/
9	Multiple drug abuse/ or Polydrug abuse/
10	Neonatal abstinence syndrome/
11	Psychoses, substance-induced/
12	Substance abuse, intravenous/
13	Substance abuse, perinatal/
14	Substance withdrawal syndrome/
15	(((stimulant\$ or polydrug\$ or drug\$1 or substance) adj3 (abstain\$ or absti-
	nen\$ or abus\$ or addict\$ or (excessive adj use\$) or dependen\$ or disorder\$
	or intoxicat\$ or misuse\$ or over dos\$ or overdos\$ or (use\$ adj (disorder\$ or
	illicit)) or withdraw\$)) or (drug\$1 adj user\$)).tw.
16	or/1-15
17	exp amphetamines/ or exp amphetamine derivative/
18	exp Cannabis/
19	exp CNS stimulating drugs/ or exp central nervous system stimulants/ or
	exp central stimulant agent/ or exp psychostimulant agent/
20	exp Cocaine/
21	Diamorphine/ or exp Heroin/
22	exp Methadone/
23	exp Narcotic agent/ or exp Narcotics/
24	Naltrexone\$.sh.
25	exp Opiate/ or exp Opiates/ or exp Opium/
26	(amphetamine\$ or crank or dextroamphetamine\$ or methamphetamine\$ or
	speed or uppers).tw.

- 27 (Adrafinil\$ or Amphetaminil\$ or Butanamine\$ or Benzphetamine\$ or Bromantan\$ or Chloramphetamine\$ or Deanol\$ or Dexamphetamine\$ or Dexmethylphenidate\$ or Dimethoxy or Methylamphetamine\$ or Hydroxyamphetamine\$ or Lefetamine\$ or Meclofenoxate\$ or Mefexamide\$ or Methcathinone\$ or Methoxyamphetamine\$ or Methylphenidate\$ or Modafinil\$ or Pemoline\$ or Picamilon\$ or Sydnocarb\$ or Sydnofen\$ or Tetrabenazine\$).mp.
- 28 (Butanamine\$ or Methylamphetamine\$ or Methylenedioxymethamphetamine\$ or Ethylbarbituric Acid\$ or Allylglycine\$ or Amfonelic Acid\$ or Amiphenazole\$ or Apomorphine\$ or Bemegride\$ or Benzphetamine\$ or Brucine\$ or Carphedon\$ or Cathinone\$ or Chloramphetamine\$ or Convulsant Agent or Cropropamide\$ or Crotetamide\$ or Dexamphetamine\$ or Dexoxadrol\$ or Dextroamphetamine\$ or Dimefline\$ or Dimetamfetamine\$ or Doxapram\$ or Ephedrine\$ or Etamivan\$ or Ethimizole\$ Methylenedioxyamphetamine\$ or Fencamfamin\$ or Fenetylline\$ or Flurothyl\$ or Fominoben\$ or Harmaline\$ or Homococaine\$ or Hydroxyamphetamine\$ or Lobeline\$ Mazindol\$ or Meclofenoxate\$ or Mefexamide\$ or Methamphetamine\$ or Methcathinone\$ or Methylephedrine\$ or Methylphenidate\$ or Ethylamphetamine\$ or Nikethamide\$ or Norcocaine\$ or Pemoline\$ or Pentetrazole\$ or Phenmetrazine\$ or Phentermine\$ or Picrotoxin\$ or Pipradol\$ or Prethcamide\$ or Prolintane\$ or Pseudoephedrine\$ or Pyrovalerone\$ Racephedrine\$ or Strychnine\$ or Butylbicycloorthobenzoate\$ or Butylbicyclophosphorothioate\$ or Tetramethylsuccinimide\$ or Theodrenaline\$).mp.
- 29 (analeptic\$ or psychostimulant\$ or stimulant\$).tw.
- 30 (cannabis or hashish or marihuana or marijua\$).mp.
- 31 (cocaine or crack).tw.
- 32 (diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine).mp.
- 33 (heroin or diacetylmorphine or diamorphine or morphin\$ or morfin\$ or smack).tw.
- 34 methadone.tw.
- 35 (antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex).tw.
- 36 (opiate\$ or opioid\$ or opium).mp.
- 37 (ardinex or codein\$ or isocodein\$ or codipertussin or codyl or methyl morfine or methylmorfine or methyl morphine or methylmorphine or morphine 3 methyl ether or morphine methyl ether or morphine monomethyl ether or pentuss or trans codeine or 467-15-2).mp,rn.
- 38 (dihydrocodeine or codhydrin\$ or codicontin or cohydrin or dehacodin or Df 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein\$ or napacodin or novicodin or paracodein or paracodin or paracodin or paracodin or remedacen or tiamon mono or 5965-13-9).mp,rn.
- 39 or/17-38

- 40 (abstain\$ or abstinen\$ or abus\$ or addict\$ or (drug adj use\$) or (excessive adj use\$) or dependen\$ or (inject\$ adj2 drug\$) or intoxicat\$ or misus\$ or over dos\$ or overdos\$ or (use\$ adj (disorder\$ or illicit)) or withdraw\$).mp.
- 41 and/39-40
- 42 or/16,41
- b. Cochrane Database of Systematic Reviews Wiley Interscience interface
- #1 MeSH descriptor Amphetamine-Related Disorders, this term only in MeSH products
- #2 MeSH descriptor Substance-Related Disorders, this term only in MeSH products
- #3 MeSH descriptor Cocaine-Related Disorders, this term only in MeSH products
- #4 MeSH descriptor Marijuana Abuse, this term only in MeSH products
- #5 MeSH descriptor Neonatal Abstinence Syndrome, this term only in MeSH products
- #6 MeSH descriptor Opioid-Related Disorders explode all trees in MeSH products
- #7 MeSH descriptor Psychoses, Substance-Induced, this term only in MeSH products
- #8 MeSH descriptor Substance Abuse, Intravenous, this term only in MeSH products
- #9 MeSH descriptor Substance Withdrawal Syndrome, this term only in MeSH products
- #10 (stimulant* or polydrug* or drug* or substance) near (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or over dos* or overdos* or withdraw*) in All Fields in all products
- #11 drug user* in All Fields in all products
- #12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
- #13 MeSH descriptor Amphetamines explode all trees in MeSH products
- #14 MeSH descriptor Cannabis, this term only in MeSH products
- #15 MeSH descriptor Central Nervous System Stimulants explode all trees in MeSH products
- #16 MeSH descriptor Cocaine explode all trees in MeSH products
- #17 MeSH descriptor Heroin, this term only in MeSH products
- #18 MeSH descriptor Methadone explode all trees in MeSH products
- #19 MeSH descriptor Narcotics explode all trees in MeSH products
- #20 MeSH descriptor Opium explode all trees in MeSH products
- #21 amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed in All Fields in all products
- #22 Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine* or Dexmethylphenidate* or Dimethoxy or Methylamphetamine* or Hydroxyamphetamine* or Lefetamine* or Meclofenoxate*

- or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine* in All Fields in all products
- #23 Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric Acid* or Allylglycine* or Amfonelic Acid* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant Agent* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexoxadrol* or Dextroamphetamine* or Dimefline* or Dimetamfetamine* or Doxapram* or Ephedrine* or Etamivan* or Ethimizole* or Methylenedioxyamphetamine* in All Fields in all products
- #24 Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* or Homococaine* or Hydroxyamphetamine* or Lobeline* or Mazindol* or Meclofenoxate* or Mefexamide* or Methamphetamine* or Methcathinone* or Methylephedrine* or Methylphenidate* or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin* or Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* or Pyrovalerone* or Racephedrine* or Strychnine* or Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* or Tetramethylsuccinimide* or Theodrenaline* in All Fields in all products
- #25 analeptic* or psychostimulant* or stimulant* in All Fields in all products
- #26 cannabis or hashish or marihuana or marijua* in All Fields in all products
- #27 cocaine or crack in All Fields in all products
- #28 diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine in All Fields in all products
- #29 heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack in All Fields in all products
- #30 methadone in All Fields in all products
- #31 antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex in All Fields in all products
- #32 opiate* or opioid* or opium in All Fields in all products
- #33 ardinex or codein* or isocodein* or codipertussin or codyl or methylmorfine or methylmorphine or morphin* or pentuss in All Fields in all products
- #34 dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or Df
 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or
 hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or
 tiamon mono in All Fields in all products
- #35 (#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)
- #36 (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)

- #37 (#35 OR #36)
- #38 abstain* or abstinen* or abus* or addict* or drug user* or dependen* or inject* drug* or intoxicat* or misus* or overdos* or illicit use* or withdraw* in All Fields in all products
- #39 (#37 AND #38)
- #40 (#12 OR #39)
- c. Database of Abstracts of Reviews of Effects Wiley Interscience interface
- #1 MeSH descriptor Amphetamine-Related Disorders, this term only in MeSH products
- #2 MeSH descriptor Substance-Related Disorders, this term only in MeSH products
- #3 MeSH descriptor Cocaine-Related Disorders, this term only in MeSH products
- #4 MeSH descriptor Marijuana Abuse, this term only in MeSH products
- #5 MeSH descriptor Neonatal Abstinence Syndrome, this term only in MeSH products
- #6 MeSH descriptor Opioid-Related Disorders explode all trees in MeSH products
- #7 MeSH descriptor Psychoses, Substance-Induced, this term only in MeSH products
- #8 MeSH descriptor Substance Abuse, Intravenous, this term only in MeSH products
- #9 MeSH descriptor Substance Withdrawal Syndrome, this term only in MeSH products
- #10 (stimulant* or polydrug* or drug* or substance) near (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or over dos* or overdos* or withdraw*) in All Fields in all products
- #11 drug user* in All Fields in all products
- #12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
- #13 MeSH descriptor Amphetamines explode all trees in MeSH products
- #14 MeSH descriptor Cannabis, this term only in MeSH products
- #15 MeSH descriptor Central Nervous System Stimulants explode all trees in MeSH products
- #16 MeSH descriptor Cocaine explode all trees in MeSH products
- #17 MeSH descriptor Heroin, this term only in MeSH products
- #18 MeSH descriptor Methadone explode all trees in MeSH products
- #19 MeSH descriptor Narcotics explode all trees in MeSH products
- #20 MeSH descriptor Opium explode all trees in MeSH products
- #21 amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed in All Fields in all products
- #22 Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine*

- or Dexmethylphenidate* or Dimethoxy or Methylamphetamine* or Hydroxyamphetamine* or Lefetamine* or Meclofenoxate* or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine* in All Fields in all products
- #23 Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric Acid* or Allylglycine* or Amfonelic Acid* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant Agent* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexamphetamine* or Dexamphetamine* or Dimefline* or Dimetamfetamine* or Doxapram* or Ephedrine* or Etamivan* or Ethimizole* or Methylenedioxyamphetamine* in All Fields in all products
- #24 Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* Homococaine* or Hydroxyamphetamine* or Mazindol* or Meclofenoxate* or Mefexamide* or Methamphetamine* or Methcathinone* or Methylephedrine* or Methylphenidate* or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin* or Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* or Pvrovalerone* Racephedrine* or Strychnine* Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* Tetramethylsuccinimide* or Theodrenaline* in All Fields in all products
- #25 analeptic* or psychostimulant* or stimulant* in All Fields in all products
- #26 cannabis or hashish or marihuana or marijua* in All Fields in all products
- #27 cocaine or crack in All Fields in all products
- #28 diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine in All Fields in all products
- #29 heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack in All Fields in all products
- #30 methadone in All Fields in all products
- #31 antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex in All Fields in all products
- #32 opiate* or opioid* or opium in All Fields in all products
- #33 ardinex or codein* or isocodein* or codipertussin or codyl or methylmorfine or methylmorphine or morphin* or pentuss in All Fields in all products
- #34 dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or Df
 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or
 hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or
 tiamon mono in All Fields in all products

- #35 (#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)
- #36 (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)
- #37 (#35 OR #36)
- #38 abstain* or abstinen* or abus* or addict* or drug user* or dependen* or inject* drug* or intoxicat* or misus* or overdos* or illicit use* or withdraw* in All Fields in all products
- #39 (#37 AND #38)
- #40 (#12 OR #39)
- d. Cochrane Central Register of Controlled Trials Wiley Interscience interface
- #1 MeSH descriptor Amphetamine-Related Disorders, this term only in MeSH products
- #2 MeSH descriptor Substance-Related Disorders, this term only in MeSH products
- #3 MeSH descriptor Cocaine-Related Disorders, this term only in MeSH products
- #4 MeSH descriptor Marijuana Abuse, this term only in MeSH products
- #5 MeSH descriptor Neonatal Abstinence Syndrome, this term only in MeSH products
- #6 MeSH descriptor Opioid-Related Disorders explode all trees in MeSH products
- #7 MeSH descriptor Psychoses, Substance-Induced, this term only in MeSH products
- #8 MeSH descriptor Substance Abuse, Intravenous, this term only in MeSH products
- #9 MeSH descriptor Substance Withdrawal Syndrome, this term only in MeSH products
- #10 (stimulant* or polydrug* or drug* or substance) near (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or over dos* or verdos* or withdraw*) in All Fields in all products
- #11 drug user* in All Fields in all products
- #12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
- #13 MeSH descriptor Amphetamines explode all trees in MeSH products
- #14 MeSH descriptor Cannabis, this term only in MeSH products
- #15 MeSH descriptor Central Nervous System Stimulants explode all trees in MeSH products
- #16 MeSH descriptor Cocaine explode all trees in MeSH products
- #17 MeSH descriptor Heroin, this term only in MeSH products
- #18 MeSH descriptor Methadone explode all trees in MeSH products
- #19 MeSH descriptor Narcotics explode all trees in MeSH products
- #20 MeSH descriptor Opium explode all trees in MeSH products
- #21 amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed in All Fields in all products

- #22 Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine* or Dexamethylphenidate* or Dimethoxy or Methylamphetamine* or Hydroxyamphetamine* or Lefetamine* or Meclofenoxate* or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine* in All Fields in all products
- #23 Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric Acid* or Allylglycine* or Amfonelic Acid* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant Agent* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexamphetamine* or Dexamphetamine* or Dimetline* or Dimetline* or Dimetline* or Dimetline* or Dimetline* or Dimetline* or Methylenedioxyamphetamine* in All Fields in all products
- #24 Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* or Homococaine* or Hydroxyamphetamine* or Lobeline* or Mazindol* or Meclofenoxate* or Mefexamide* or Methamphetamine* or Methcathinone* or Methylephedrine* or Methylphenidate* or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin* or Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* or Pyrovalerone* or Racephedrine* or Strychnine* or Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* or Tetramethylsuccinimide* or Theodrenaline* in All Fields in all products
- #25 analeptic* or psychostimulant* or stimulant* in All Fields in all products
- #26 cannabis or hashish or marihuana or marijua* in All Fields in all products
- #27 cocaine or crack in All Fields in all products
- #28 diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine in All Fields in all products
- #29 heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack in All Fields in all products
- #30 methadone in All Fields in all products
- #31 antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex in All Fields in all products
- #32 opiate* or opioid* or opium in All Fields in all products
- #33 ardinex or codein* or isocodein* or codipertussin or codyl or methylmorfine or methylmorphine or morphin* or pentuss in All Fields in all products
- #34 dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or Df 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or tiamon mono in All Fields in all products

- #35 (#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)
- #36 (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)
- #37 (#35 OR #36)
- #38 abstain* or abstinen* or abus* or addict* or drug user* or dependen* or inject* drug* or intoxicat* or misus* or overdos* or illicit use* or withdraw* in All Fields in all products
- #39 (#37 AND #38)
- #40 (#12 OR #39)

2. SYSTEMATIC REVIEW SEARCH FILTERS

- a. MEDLINE, EMBASE, PsycINFO, CINAHL Ovid interface
- exp meta analysis/ or exp systematic review/ or exp literature review/ or exp literature searching/ or exp cochrane library/ or exp review literature/
- 2 ((systematic or quantitative or methodologic\$) adj5 (overview\$ or review\$)).mp.
- 3 (metaanaly\$ or meta analy\$).mp.
- 4 (research adj (review\$ or integration)).mp.
- 5 reference list\$.ab.
- 6 bibliograph\$.ab.
- 7 published studies.ab.
- 8 relevant journals.ab.
- 9 selection criteria.ab.
- 10 (data adj (extraction or synthesis)).ab.
- 11 ((handsearch\$3 or (hand or manual)) adj search\$).tw.
- 12 ((mantel adj haenszel) or peto or dersimonian or der simonian).tw.
- 13 (fixed effect\$ or random effect\$).tw.
- review\$.pt,mp. and (bids or cochrane or index medicus or isi citation or medlars or psyclit or psychlit or scisearch or science citation or web adj1 science).mp.
- 15 (systematic\$ or meta\$).pt.
- 16 or/1-15

3. RCTS SEARCH FILTERS

- a. MEDLINE, EMBASE, PsycINFO, CINAHL Ovid interface
- 1 exp clinical trials/ or exp clinical trials/ or exp controlled clinical trials/
- 2 exp crossover procedure/ or exp cross over studies/ or exp crossover design/
- 3 exp double blind procedure/ or exp double blind method/ or exp double blind studies/ or exp single blind procedure/ or exp single blind method/ or exp single blind studies/

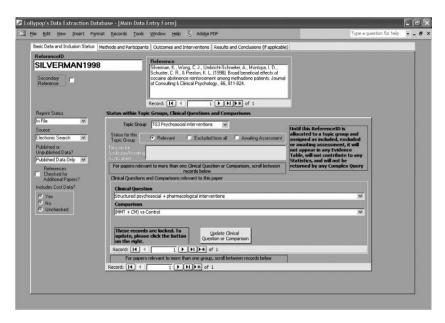
- 4 exp random allocation/ or exp randomization/ or exp random assignment/ or exp random sample/ or exp random sampling/
- 5 exp randomized controlled trials/ or exp randomized controlled trial/
- 6 (clinical adj2 trial\$).tw.
- 7 (crossover or cross over).tw.
- 8 (((single\$ or doubl\$ or trebl\$ or tripl\$) adj5 (blind\$ or mask\$ or dummy)) or (singleblind\$ or doubleblind\$ or trebleblind\$)).tw.
- 9 (placebo\$ or random\$).mp.
- 10 (clinical trial\$ or clinical control trial or random\$).pt.
- animals/ not (animals/ and human\$.mp.)
- animal\$/ not (animal\$/ and human\$/)
- 13 (animal not (animal and human)).po.
- 14 (or/1-10) not (or/11-13)

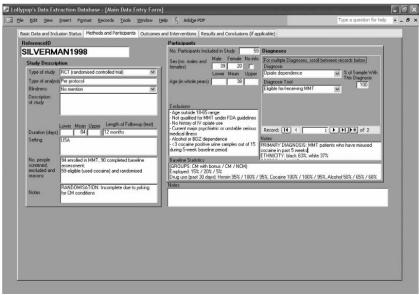
Details of additional searches undertaken to support the development of this guideline are available on request.

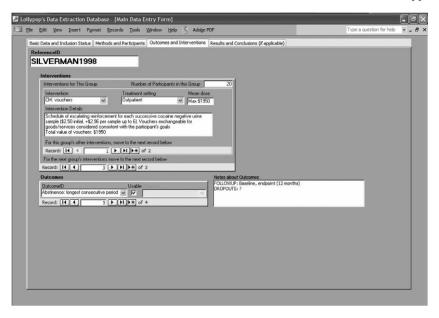
APPENDIX 8:

CLINICAL STUDY DATA EXTRACTION FORM

Information about each study was entered into an Access database using specially designed forms (see below for an example).







APPENDIX 9:

QUALITY CHECKLISTS FOR CLINICAL STUDIES AND REVIEWS

The methodological quality of each study was evaluated using dimensions adapted from SIGN (SIGN, 2002). SIGN originally adapted its quality criteria from checklists developed in Australia (Liddel *et al.*, 1996). Both groups reportedly undertook extensive development and validation procedures when creating their quality criteria.

Quality (Checklist for a Systematic Review or M	1eta-Analysis		
Study ID	:	·		
Guideline topic:		Key question no:		
Checklist	t completed by:			
SECTION	N 1: INTERNAL VALIDITY			
In a well-	-conducted systematic review:	In this study this criteri (Circle one option for each		
1.1	The study addresses an appropriate and clearly focused question.	Well covered Not addressed Adequately addressed Not reported Poorly addressed Not applicable		
1.2	A description of the methodology used is included.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable	
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable	
1.4	Study quality is assessed and taken into account.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable	
1.5	There are enough similarities between the studies selected to make combining them reasonable.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable	
SECTION	N 2: OVERALL ASSESSMENT OF THE	STUDY		
2.1	How well was the study done to minimise bias? <i>Code</i> ++, + <i>or</i> -			

NOTES ON THE USE OF THE METHODOLOGY CHECKLIST: SYSTEMATIC REVIEWS AND META-ANALYSES

Section 1 identifies the study and asks a series of questions aimed at establishing the internal validity of the study under review – that is, making sure that it has been carried out carefully and that the outcomes are likely to be attributable to the intervention being investigated. Each question covers an aspect of methodology that research has shown makes a significant difference to the conclusions of a study.

For each question in this section, one of the following should be used to indicate how well it has been addressed in the review:

- well covered
- adequately addressed
- poorly addressed
- not addressed (that is, not mentioned or indicates that this aspect of study design was ignored)
- not reported (that is, mentioned but insufficient detail to allow assessment to be made)
- not applicable.

1.1 THE STUDY ADDRESSES AN APPROPRIATE AND CLEARLY FOCUSED OUESTION

Unless a clear and well-defined question is specified in the report of the review, it will be difficult to assess how well it has met its objectives or how relevant it is to the question to be answered on the basis of the conclusions.

1.2 A DESCRIPTION OF THE METHODOLOGY USED IS INCLUDED

One of the key distinctions between a systematic review and a general review is the systematic methodology used. A systematic review should include a detailed description of the methods used to identify and evaluate individual studies. If this description is not present, it is not possible to make a thorough evaluation of the quality of the review, and it should be rejected as a source of level-1 evidence (though it may be useable as level-4 evidence, if no better evidence can be found).

1.3 THE LITERATURE SEARCH IS SUFFICIENTLY RIGOROUS TO IDENTIFY ALL THE RELEVANT STUDIES

A systematic review based on a limited literature search – for example, one limited to MEDLINE only – is likely to be heavily biased. A well-conducted review should as a minimum look at EMBASE and MEDLINE and, from the late 1990s onward, the

Cochrane Library. Any indication that hand searching of key journals, or follow-up of reference lists of included studies, were carried out in addition to electronic database searches can normally be taken as evidence of a well-conducted review.

1.4 STUDY QUALITY IS ASSESSED AND TAKEN INTO ACCOUNT

A well-conducted systematic review should have used clear criteria to assess whether individual studies had been well conducted before deciding whether to include or exclude them. If there is no indication of such an assessment, the review should be rejected as a source of level-1 evidence. If details of the assessment are poor, or the methods are considered to be inadequate, the quality of the review should be downgraded. In either case, it may be worthwhile obtaining and evaluating the individual studies as part of the review being conducted for this guideline.

1.5 THERE ARE ENOUGH SIMILARITIES BETWEEN THE STUDIES SELECTED TO MAKE COMBINING THEM REASONABLE

Studies covered by a systematic review should be selected using clear inclusion criteria (see question 1.4 above). These criteria should include, either implicitly or explicitly, the question of whether the selected studies can legitimately be compared. It should be clearly ascertained, for example, that the populations covered by the studies are comparable, that the methods used in the investigations are the same, that the outcome measures are comparable and the variability in effect sizes between studies is not greater than would be expected by chance alone.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on the responses in Section 1 and using the following coding system:

++	All or most of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study or review are thought very unlikely to alter.	
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.	
_	Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.	

Quali	ity Checklist for an RCT				
Study					
Guid	eline topic:		Key question no:		
	Checklist completed by:				
	TION 1: INTERNAL VALIDITY				
In a v	vell-conducted RCT study:		this study this crite tion for each questi		(Circle one
1.1	The study addresses an appropriate and clearly focused question.	Ad	ell covered equately addressed orly addressed	Not rej	dressed ported plicable
1.2	The assignment of subjects to treatment groups is randomised.	Ad	ell covered equately addressed orly addressed	Not rep	dressed ported plicable
1.3	An adequate concealment method is used.	Ad	ell covered equately addressed orly addressed	Not rej	dressed ported plicable
1.4	Subjects and investigators are kept 'blind'about treatment allocation.	Ad	ell covered equately addressed orly addressed	Not rep	dressed ported plicable
1.5	The treatment and control groups are similar at the start of the trial.	Ad	ell covered equately addressed orly addressed	Not rej	dressed ported plicable
1.6	The only difference between groups is the treatment under investigation.	Ad	ell covered equately addressed orly addressed	Not rej	dressed ported plicable
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Ad	ell covered equately addressed orly addressed	Not rep	dressed ported plicable
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?				
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention-to-treat analysis).	Ad	ell covered equately addressed orly addressed	Not rep	dressed ported plicable
1.10	Where the study is carried out at more than one site, results are comparable for all sites.	Ad Poo	ell covered equately addressed orly addressed	Not rej	dressed ported plicable
SECT	TION 2: OVERALL ASSESSMENT OF TH	E S	ΓUDY		
2.1	How well was the study done to minimise bias? Code ++, + or-				

NOTES ON THE USE OF THE METHODOLOGY CHECKLIST: RCTS

Section 1 identifies the study and asks a series of questions aimed at establishing the internal validity of the study under review – that is, making sure that it has been carried out carefully and that the outcomes are likely to be attributable to the intervention being investigated. Each question covers an aspect of methodology that research has shown makes a significant difference to the conclusions of a study.

For each question in this section, one of the following should be used to indicate how well it has been addressed in the review:

- well covered
- adequately addressed
- poorly addressed
- not addressed (that is, not mentioned or indicates that this aspect of study design was ignored)
- not reported (that is, mentioned but insufficient detail to allow assessment to be made)
- not applicable.

1.1 THE STUDY ADDRESSES AN APPROPRIATE AND CLEARLY FOCUSED QUESTION

Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question to be answered on the basis of its conclusions.

1.2 THE ASSIGNMENT OF SUBJECTS TO TREATMENT GROUPS IS RANDOMISED

Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study. If there is no indication of randomisation, the study should be rejected. If the description of randomisation is poor, or the process used is not truly random (for example, allocation by date or alternating between one group and another) or can otherwise be seen as flawed, the study should be given a lower quality rating.

1.3 AN ADEQUATE CONCEALMENT METHOD IS USED

Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%. Centralised allocation, computerised allocation systems or the use of coded identical containers would all be regarded as adequate methods of concealment and may be taken as indicators of a

well-conducted study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating, and can be rejected if the concealment method is seen as inadequate.

1.4 SUBJECTS AND INVESTIGATORS ARE KEPT 'BLIND' ABOUT TREATMENT ALLOCATION

Blinding can be carried out up to three levels. In single-blind studies, patients are unaware of which treatment they are receiving; in double-blind studies, the doctor and the patient are unaware of which treatment the patient is receiving; in triple-blind studies, patients, healthcare providers and those conducting the analysis are unaware of which patients receive which treatment. The higher the level of blinding, the lower the risk of bias in the study.

1.5 THE TREATMENT AND CONTROL GROUPS ARE SIMILAR AT THE START OF THE TRIAL

Patients selected for inclusion in a trial should be as similar as possible, in order to eliminate any possible bias. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin or comorbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

1.6 THE ONLY DIFFERENCE BETWEEN GROUPS IS THE TREATMENT UNDER INVESTIGATION

If some patients receive additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups are not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence, it should be treated with caution and given a low quality rating.

1.7 ALL RELEVANT OUTCOMES ARE MEASURED IN A STANDARD, VALID AND RELIABLE WAY

If some significant clinical outcomes have been ignored, or not adequately taken into account, the study should be downgraded. It should also be downgraded if the measures used are regarded as being doubtful in any way or applied inconsistently.

1.8 WHAT PERCENTAGE OF THE INDIVIDUALS OR CLUSTERS RECRUITED INTO EACH TREATMENT ARM OF THE STUDY DROPPED OUT BEFORE THE STUDY WAS COMPLETED?

The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop-out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients drop out, as well as how many. It should be noted that the drop-out rate may be expected to be higher in studies conducted over a long period of time. A higher drop-out rate will normally lead to downgrading, rather than rejection, of a study.

1.9 ALL THE SUBJECTS ARE ANALYSED IN THE GROUPS TO WHICH THEY WERE RANDOMLY ALLOCATED (OFTEN REFERRED TO AS INTENTION-TO-TREAT ANALYSIS)

In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated, irrespective of the treatment they actually received. (This is known as intention-to-treat analysis.) If it is clear that analysis is not on an intention-to-treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

1.10 WHERE THE STUDY IS CARRIED OUT AT MORE THAN ONE SITE, RESULTS ARE COMPARABLE FOR ALL SITES

In multi-site studies, confidence in the results should be increased if it can be shown that similar results have been obtained at the different participating centres.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on the responses in Section 1 and using the following coding system:

++	All or most of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study or review are thought very unlikely to alter.	
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.	
_	Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.	

Qual	ity Checklist for a Cohort Study*			
Study ID:		Relevant questions:		
•		•		
Guideline topic:		-		
Chec	klist completed by:	-		
SECT	TION 1: INTERNAL VALIDITY			
In a v	vell-conducted cohort study:	In this study the criterion is:		
		(Circle one option for ea	ach question)	
1.1	The study addresses an appropriate and	Well covered	Not addressed	
	clearly focused question.	Adequately addressed	Not reported	
		Poorly addressed	Not applicable	
SELE	CTION OF SUBJECTS			
1.2	The two groups being studied are selected	Well covered	Not addressed	
	from source populations that are comparable	Adequately addressed	Not reported	
	in all respects other than the factor under	Poorly addressed	Not applicable	
	investigation.	•	* *	
1.3	The study indicates how many of the people	Well covered	Not addressed	
	asked to take part did so, in each of the	Adequately addressed	Not reported	
	groups being studied.	Poorly addressed	Not applicable	
1.4	The likelihood that some eligible subjects	Well covered	Not addressed	
	might have the outcome at the time of	Adequately addressed	Not reported	
	enrolment is assessed and taken into account	Poorly addressed	Not applicable	
	in the analysis.	1 oorly addressed	Not applicable	
1.5	What percentage of individuals or clusters			
1.0	recruited into each arm of the study dropped			
	out before the study was completed?			
	out before the study was completed:			
1.6	Comparison is made between full	Well covered	Not addressed	
	participants and those lost to follow-up, by	Adequately addressed	Not reported	
	exposure status.	Poorly addressed	Not applicable	
ASSE	SSMENT	<u> </u>	**	
1.7	The outcomes are clearly defined.	Well covered	Not addressed	
	·	Adequately addressed	Not reported	
		Poorly addressed	Not applicable	
1.8	The assessment of outcome is made blind to	Well covered	Not addressed	
	exposure status.	Adequately addressed	Not reported	
	T	Poorly addressed	Not applicable	
1.9	Where blinding was not possible, there is	Well covered	Not addressed	
	some recognition that knowledge of exposure		Not reported	
	status could have influenced the assessment	Poorly addressed	Not applicable	
	of outcome.		applicable	
1.10	The measure of assessment of exposure is	Well covered	Not addressed	
	reliable.	Adequately addressed	Not reported	
		Poorly addressed	Not applicable	
1.11	Evidence from other sources is used to	Well covered	Not addressed	
	demonstrate that the method of outcome	Adequately addressed	Not reported	
	assessment is valid and reliable.	Poorly addressed	Not applicable	
1.12	Exposure level or prognostic factor is	Well covered	Not addressed	
1.14	assessed more than once.	Adequately addressed	Not reported	
	accessed more than once.	Poorly addressed	Not reported Not applicable	
		1 corry addressed	1 tot applicable	

CON	CONFOUNDING				
1.13	The main potential confounders are	Well covered	Not addressed		
	identified and taken into account in the	Adequately addressed	Not reported		
	design and analysis.	Poorly addressed	Not applicable		
STAT	TISTICAL ANALYSIS				
1.14	Have confidence intervals been provided?				
	_				
SECT	TION 2: OVERALL ASSESSMENT OF THE ST	ΓUDY			
2.1	How well was the study done to minimise the	risk of			
	bias or confounding, and to establish a causal				
	relationship between exposure and effect?				
	Code ++, + or -				

^{*}A cohort study can be defined as a retrospective or prospective follow-up study. Groups of individuals are defined on the basis of the presence or absence of exposure to a suspected risk factor or intervention. This checklist is not appropriate for assessing uncontrolled studies (for example, a case series where there is no comparison [control] group of patients.

NOTES ON THE USE OF THE METHODOLOGY CHECKLIST: COHORT STUDIES

The studies covered by this checklist are designed to answer questions of the type 'What are the effects of this exposure?' It relates to studies that compare a group of people with a particular exposure with another group who either have not had the exposure or have a different level of exposure. Cohort studies may be prospective (where the exposure is defined and subjects selected before outcomes occur) or retrospective (where exposure is assessed after the outcome is known, usually by the examination of medical records). Retrospective studies are generally regarded as a weaker design, and should not receive a 2++ rating.

Section 1 identifies the study and asks a series of questions aimed at establishing the internal validity of the study under review – that is, making sure that it has been carried out carefully, and that the outcomes are likely to be attributable to the intervention being investigated. Each question covers an aspect of methodology that has been shown to make a significant difference to the conclusions of a study.

Because of the potential complexity and subtleties of the design of this type of study, there are comparatively few criteria that automatically rule out use of a study as evidence. It is more a matter of increasing confidence in the likelihood of a causal relationship existing between exposure and outcome by identifying how many aspects of good study design are present and how well they have been tackled. A study that fails to address or report on more than one or two of the questions considered below should almost certainly be rejected.

For each question in this section, one of the following should be used to indicate how well it has been addressed in the review:

- well covered
- adequately addressed

- poorly addressed
- not addressed (that is, not mentioned or indicates that this aspect of study design was ignored)
- not reported (that is, mentioned but insufficient detail to allow assessment to be made)
- not applicable

1.1 THE STUDY ADDRESSES AN APPROPRIATE AND CLEARLY FOCUSED OUESTION

Unless a clear and well-defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question to be answered on the basis of its conclusions.

1.2 THE TWO GROUPS BEING STUDIED ARE SELECTED FROM SOURCE POPULATIONS THAT ARE COMPARABLE IN ALL RESPECTS OTHER THAN THE FACTOR UNDER INVESTIGATION

Study participants may be selected from the target population (all individuals to which the results of the study could be applied), the source population (a defined subset of the target population from which participants are selected) or from a pool of eligible subjects (a clearly defined and counted group selected from the source population). It is important that the two groups selected for comparison are as similar as possible in all characteristics except for their exposure status or the presence of specific prognostic factors or prognostic markers relevant to the study in question. If the study does not include clear definitions of the source populations and eligibility criteria for participants, it should be rejected.

1.3 THE STUDY INDICATES HOW MANY OF THE PEOPLE ASKED TO TAKE PART DID SO IN EACH OF THE GROUPS BEING STUDIED

This question relates to what is known as the participation rate, defined as the number of study participants divided by the number of eligible subjects. This should be calculated separately for each branch of the study. A large difference in participation rate between the two arms of the study indicates that a significant degree of selection bias may be present, and the study results should be treated with considerable caution.

1.4 THE LIKELIHOOD THAT SOME ELIGIBLE SUBJECTS MIGHT HAVE THE OUTCOME AT THE TIME OF ENROLMENT IS ASSESSED AND TAKEN INTO ACCOUNT IN THE ANALYSIS

If some of the eligible subjects, particularly those in the unexposed group, already have the outcome at the start of the trial, the final result will be biased. A well-conducted study will attempt to estimate the likelihood of this occurring and take it into account in the analysis through the use of sensitivity studies or other methods.

1.5 WHAT PERCENTAGE OF INDIVIDUALS OR CLUSTERS RECRUITED INTO EACH ARM OF THE STUDY DROPPED OUT BEFORE THE STUDY WAS COMPLETED?

The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop-out rate is regarded as acceptable, but in observational studies conducted over a lengthy period of time a higher drop-out rate is to be expected. A decision on whether to downgrade or reject a study because of a high drop-out rate is a matter of judgement based on the reasons why people drop out and whether drop-out rates are comparable in the exposed and unexposed groups. Reporting of efforts to follow up participants that drop out may be regarded as an indicator of a well-conducted study.

1.6 COMPARISON IS MADE BETWEEN FULL PARTICIPANTS AND THOSE LOST TO FOLLOW-UP BY EXPOSURE STATUS

For valid study results, it is essential that the study participants are truly representative of the source population. It is always possible that participants who drop out of the study will differ in some significant way from those who remain part of the study throughout. A well-conducted study will attempt to identify any such differences between full and partial participants in both the exposed and unexposed groups. Any indication that differences exist should lead to the study results being treated with caution.

1.7 THE OUTCOMES ARE CLEARLY DEFINED

Once enrolled in the study, participants should be followed until specified end points or outcomes are reached. In a study of the effect of exercise on the death rates from heart disease in middle-aged men, for example, participants might be followed up until death, reaching a predefined age or until completion of the study. If outcomes and the criteria used for measuring them are not clearly defined, the study should be rejected.

1.8 THE ASSESSMENT OF OUTCOME IS MADE BLIND TO EXPOSURE STATUS

If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is done should be rated more highly than those where it is not done or not done adequately.

1.9 WHERE BLINDING WAS NOT POSSIBLE, THERE IS SOME RECOGNITION THAT KNOWLEDGE OF EXPOSURE STATUS COULD HAVE INFLUENCED THE ASSESSMENT OF OUTCOME

Blinding is not possible in many cohort studies. In order to assess the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups – for example, frequency of observations, who carried out the observations and the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

1.10 THE MEASURE OF ASSESSMENT OF EXPOSURE IS RELIABLE

A well-conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study.

1.11 EVIDENCE FROM OTHER SOURCES IS USED TO DEMONSTRATE THAT THE METHOD OF OUTCOME ASSESSMENT IS VALID AND RELIABLE

The inclusion of evidence from other sources or previous studies that demonstrate the validity and reliability of the assessment methods used should further increase confidence in study quality.

1.12 EXPOSURE LEVEL OR PROGNOSTIC FACTOR IS ASSESSED MORE THAN ONCE

Confidence in data quality should be increased if exposure level or the presence of prognostic factors is measured more than once. Independent assessment by more than one investigator is preferable.

1.13 THE MAIN POTENTIAL CONFOUNDERS ARE IDENTIFIED AND TAKEN INTO ACCOUNT IN THE DESIGN AND ANALYSIS

Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. A study that does not address the possibility of confounding should be rejected.

1.14 HAVE CONFIDENCE INTERVALS BEEN PROVIDED?

Confidence limits are the preferred method for indicating the precision of statistical results and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with caution.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on the responses in Section 1 and using the following coding system:

++	All or most of the criteria have been fulfilled. Where they have not been fulfilled, the conclusions of the study or review are thought very unlikely to alter.
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
_	Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

APPENDIX 10:

SEARCH STRATEGIES FOR THE IDENTIFICATION OF HEALTH ECONOMICS EVIDENCE

1. GENERAL SEARCH FILTERS

Drug misuse

a.	MEDLINE, EMBASE, PsycINFO, CINAHL – Ovid interface
1	Amphetamine-related disorders/
2	Cannabis addiction/ or Marijuana abuse/
3	Cocaine dependence/ or Cocaine-related disorders/
4	Heroin addiction/
5	exp Narcotic dependence/
6	Opiate addiction/ or exp Opioid-related disorders/
7	Drug abuse/ or Drug abuse pattern/ or Drug addiction/ or Drug misuse/ o
	Drug overdoses/ or Intravenous drug abuse/ or Substance abuse/ o
	Substance-related disorders/ or "Substance use disorders"/
8	Drug dependence/ or Drug dependency/ or Substance dependence/
9	Multiple drug abuse/ or Polydrug abuse/
10	Neonatal abstinence syndrome/
11	Psychoses, substance-induced/
12	Substance abuse, intravenous/
13	Substance abuse, perinatal/
14	Substance withdrawal syndrome/
15	(((stimulant\$ or polydrug\$ or drug\$1 or substance) adj3 (abstain\$ or abstinen\$ or abus\$ or addict\$ or (excessive adj use\$) or dependen\$ or disorder\$ or intoxicat\$ or misuse\$ or over dos\$ or overdos\$ or (use\$ adj (disorder\$ o illicit)) or withdraw\$)) or (drug\$1 adj user\$)).tw.
16	or/1-15
17	exp amphetamines/ or exp amphetamine derivative/
18	exp Cannabis/
19	exp CNS stimulating drugs/ or exp central nervous system stimulants/ o exp central stimulant agent/ or exp psychostimulant agent/
20	exp Cocaine/
21	Diamorphine/ or exp Heroin/
22	exp Methadone/
23	exp Narcotic agent/ or exp Narcotics/
24	Naltrexone\$.sh.
25	exp Opiate/ or exp Opiates/ or exp Opium/
26	(amphetamine\$ or crank or dextroamphetamine\$ or methamphetamine\$ o speed or uppers).tw.

- 27 (Adrafinil\$ or Amphetaminil\$ or Butanamine\$ or Benzphetamine\$ or Bromantan\$ or Chloramphetamine\$ or Deanol\$ or Dexamphetamine\$ or Dexmethylphenidate\$ or Dimethoxy or Methylamphetamine\$ or Hydroxyamphetamine\$ or Lefetamine\$ or Meclofenoxate\$ or Mefexamide\$ or Methcathinone\$ or Methoxyamphetamine\$ or Methylphenidate\$ or Modafinil\$ or Pemoline\$ or icamilon\$ or Sydnocarb\$ or Sydnofen\$ or Tetrabenazine\$).mp.
- 28 (Butanamine\$ or Methylamphetamine\$ or Methylenedioxymethamphetamine\$ or Ethylbarbituric Acid\$ or Allylglycine\$ or Amfonelic Acid\$ or Amiphenazole\$ or Apomorphine\$ or Bemegride\$ or Benzphetamine\$ or Brucine\$ or Carphedon\$ or Cathinone\$ or Chloramphetamine\$ or Convulsant Agent or Cropropamide\$ or Crotetamide\$ or Dexamphetamine\$ Dexoxadrol\$ or Dextroamphetamine\$ Dimefline\$ Dimetamfetamine\$ or Doxapram\$ or Ephedrine\$ or Etamivan\$ or Ethimizole\$ or Methylenedioxyamphetamine\$ or Fencamfamin\$ or Fenetylline\$ or Flurothyl\$ or Fominoben\$ or Harmaline\$ or Homococaine\$ or Hydroxyamphetamine\$ or Lobeline\$ or Mazindol\$ or Meclofenoxate\$ Mefexamide\$ or Methamphetamine\$ or Methcathinone\$ or Methylephedrine\$ or Methylphenidate\$ or Ethylamphetamine\$ or Nikethamide\$ or Norcocaine\$ or Pemoline\$ or Pentetrazole\$ or Phenmetrazine\$ or Phentermine\$ or Picrotoxin\$ or Pipradol\$ or Prethcamide\$ or Prolintane\$ or Pseudoephedrine\$ or Pyrovalerone\$ or Racephedrine\$ or Strychnine\$ or Butylbicycloorthobenzoate\$ Butylbicyclophosphorothioate\$ Tetramethylsuccinimide\$ or or Theodrenaline\$).mp.
- 29 (analeptic\$ or psychostimulant\$ or stimulant\$).tw.
- 30 (cannabis or hashish or marihuana or marijua\$).mp.
- 31 (cocaine or crack).tw.
- 32 (diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine).mp.
- 33 (heroin or diacetylmorphine or diamorphine or morphin\$ or morfin\$ or smack).tw.
- 34 methadone.tw.
- 35 (antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex).tw.
- 36 (opiate\$ or opioid\$ or opium).mp.
- 37 (ardinex or codein\$ or isocodein\$ or codipertussin or codyl or methyl morfine or methylmorfine or methyl morphine or methylmorphine or morphine 3 methyl ether or morphine methyl ether or morphine monomethyl ether or pentuss or trans codeine or 467-15-2).mp,rn.
- 38 (dihydrocodeine or codhydrin\$ or codicontin or cohydrin or dehacodin or Df 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein\$ or napacodin or novicodin or paracodein or paracodin or paracodin or paracodin or paracodin or remedacen or tiamon mono or 5965-13-9).mp,rn.

- 39 or/17-38
- 40 (abstain\$ or abstinen\$ or abus\$ or addict\$ or (drug adj use\$) or (excessive adj use\$) or dependen\$ or (inject\$ adj2 drug\$) or intoxicat\$ or misus\$ or over dos\$ or overdos\$ or (use\$ adj (disorder\$ or illicit)) or withdraw\$).mp.
- 41 and/39-40
- 42 or/16,41
- b. NHS Economic Evaluation Database Wiley Interscience interface
- #1 MeSH descriptor Amphetamine-Related Disorders, this term only in MeSH products
- #2 MeSH descriptor Substance-Related Disorders, this term only in MeSH products
- #3 MeSH descriptor Cocaine-Related Disorders, this term only in MeSH products
- #4 MeSH descriptor Marijuana Abuse, this term only in MeSH products
- #5 MeSH descriptor Neonatal Abstinence Syndrome, this term only in MeSH products
- #6 MeSH descriptor Opioid-Related Disorders explode all trees in MeSH products
- #7 MeSH descriptor Psychoses, Substance-Induced, this term only in MeSH products
- #8 MeSH descriptor Substance Abuse, Intravenous, this term only in MeSH products
- #9 MeSH descriptor Substance Withdrawal Syndrome, this term only in MeSH products
- #10 (stimulant* or polydrug* or drug* or substance) near (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or over dos* or overdos* or withdraw*) in All Fields in all products
- #11 drug user* in All Fields in all products
- #12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
- #13 MeSH descriptor Amphetamines explode all trees in MeSH products
- #14 MeSH descriptor Cannabis, this term only in MeSH products
- #15 MeSH descriptor Central Nervous System Stimulants explode all trees in MeSH products
- #16 MeSH descriptor Cocaine explode all trees in MeSH products
- #17 MeSH descriptor Heroin, this term only in MeSH products
- #18 MeSH descriptor Methadone explode all trees in MeSH products
- #19 MeSH descriptor Narcotics explode all trees in MeSH products
- #20 MeSH descriptor Opium explode all trees in MeSH products
- #21 amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed in All Fields in all products
- #22 Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine* or Dexmethylphenidate* or Dimethoxy or Methylamphetamine* or

- Hydroxyamphetamine* or Lefetamine* or Meclofenoxate* or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine* in All Fields in all products
- #23 Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric Acid* or Allylglycine* or Amfonelic Acid* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant Agent* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexamphetamine* or Dexamphetamine* or Dimefline* or Dimetamfetamine* or Doxapram* or Ephedrine* or Etamivan* or Ethimizole* or Methylenedioxyamphetamine* in All Fields in all products
- #24 Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* or Homococaine* or Hydroxyamphetamine* or Lobeline* or Mazindol* Meclofenoxate* or Mefexamide* or Methamphetamine* Methylephedrine* Methcathinone* or or Methylphenidate* or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin* or Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* Pvrovalerone* or Racephedrine* or Strychnine* Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* Tetramethylsuccinimide* or Theodrenaline* in All Fields in all products
- #25 analeptic* or psychostimulant* or stimulant* in All Fields in all products
- #26 cannabis or hashish or marihuana or marijua* in All Fields in all products
- #27 cocaine or crack in All Fields in all products
- #28 diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine in All Fields in all products
- #29 heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack in All Fields in all products
- #30 methadone in All Fields in all products
- #31 antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex in All Fields in all products
- #32 opiate* or opioid* or opium in All Fields in all products
- #33 ardinex or codein* or isocodein* or codipertussin or codyl or methylmorfine or methylmorphine or morphin* or pentuss in All Fields in all products
- #34 dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or Df 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or tiamon mono in All Fields in all products
- #35 (#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)

- #36 (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)
- #37 (#35 OR #36)
- #38 abstain* or abstinen* or abus* or addict* or drug user* or dependen* or inject* drug* or intoxicat* or misus* or overdos* or illicit use* or withdraw* in All Fields in all products
- #39 (#37 AND #38)
- #40 (#12 OR #39)
- c. Health Technology Assessment Database Wiley Interscience interface
- #1 MeSH descriptor Amphetamine-Related Disorders, this term only in MeSH products
- #2 MeSH descriptor Substance-Related Disorders, this term only in MeSH products
- #3 MeSH descriptor Cocaine-Related Disorders, this term only in MeSH products
- #4 MeSH descriptor Marijuana Abuse, this term only in MeSH products
- #5 MeSH descriptor Neonatal Abstinence Syndrome, this term only in MeSH products
- #6 MeSH descriptor Opioid-Related Disorders explode all trees in MeSH products
- #7 MeSH descriptor Psychoses, Substance-Induced, this term only in MeSH products
- #8 MeSH descriptor Substance Abuse, Intravenous, this term only in MeSH products
- #9 MeSH descriptor Substance Withdrawal Syndrome, this term only in MeSH products
- #10 (stimulant* or polydrug* or drug* or substance) near (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or over dos* or overdos* or withdraw*) in All Fields in all products
- #11 drug user* in All Fields in all products
- #12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)
- #13 MeSH descriptor Amphetamines explode all trees in MeSH products
- #14 MeSH descriptor Cannabis, this term only in MeSH products
- #15 MeSH descriptor Central Nervous System Stimulants explode all trees in MeSH products
- #16 MeSH descriptor Cocaine explode all trees in MeSH products
- #17 MeSH descriptor Heroin, this term only in MeSH products
- #18 MeSH descriptor Methadone explode all trees in MeSH products
- #19 MeSH descriptor Narcotics explode all trees in MeSH products
- #20 MeSH descriptor Opium explode all trees in MeSH products
- #21 amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed in All Fields in all products
- #22 Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine*

- or Dexmethylphenidate* or Dimethoxy or Methylamphetamine* or Hydroxyamphetamine* or Lefetamine* or Meclofenoxate* or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine* in All Fields in all products
- #23 Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric Acid* or Allylglycine* or Amfonelic Acid* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant Agent* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexoxadrol* or Dextroamphetamine* or Dimefline* or Dimetamfetamine* or Doxapram* or Ephedrine* or Etamivan* or Ethimizole* or Methylenedioxyamphetamine* in All Fields in all products
- Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* #24 or Homococaine* or Hydroxyamphetamine* or Lobeline* or Mazindol* or Meclofenoxate* Mefexamide* or or Methamphetamine* Methcathinone* Methylephedrine* or Methylphenidate* or or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin* or Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* or Pyrovalerone* or Racephedrine* or Strychnine* or Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* or Tetramethylsuccinimide* or Theodrenaline* in All Fields in all products
- #25 analeptic* or psychostimulant* or stimulant* in All Fields in all products
- #26 cannabis or hashish or marihuana or marijua* in All Fields in all products
- #27 cocaine or crack in All Fields in all products
- #28 diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine in All Fields in all products
- #29 heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack in All Fields in all products
- #30 methadone in All Fields in all products
- #31 antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex in All Fields in all products
- #32 opiate* or opioid* or opium in All Fields in all products
- #33 ardinex or codein* or isocodein* or codipertussin or codyl or methylmorfine or methylmorphine or morphin* or pentuss in All Fields in all products
- #34 dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or Df 118 or Df118 or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or tiamon mono in All Fields in all products

- #35 (#13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)
- #36 (#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34)
- #37 (#35 OR #36)
- #38 abstain* or abstinen* or abus* or addict* or drug user* or dependen* or inject* drug* or intoxicat* or misus* or overdos* or illicit use* or withdraw* in All Fields in all products
- #39 (#37 AND #38)
- #40 (#12 OR #39)

d. OHE EED - Clarinet interface

- AX=(stimulant* or polydrug* or drug* or substance) and (abstain* or abstinen* or abus* or addict* or dependen* or disorder* or intoxicat* or misuse* or overdos* or withdraw*)
- 2 AX='illicit use' or 'drug use' or 'drug user' or 'drug users'
- 3 AX=amphetamine* or crank or dextroamphetamine* or methamphetamine* or speed or uppers
- 4 AX=Adrafinil* or Amphetaminil* or Butanamine* or Benzphetamine* or Bromantan* or Chloramphetamine* or Deanol* or Dexamphetamine* or Dexmethylphenidate* or Dimethoxy or Methylamphetamine* or Hydroxyamphetamine* or Lefetamine* or Meclofenoxate* or Mefexamide* or Methcathinone* or Methoxyamphetamine* or Methylamphetamine* or Methylamphetamine* or Methylphenidate* or Modafinil* or Pemoline* or Picamilon* or Sydnocarb* or Sydnofen* or Tetrabenazine*
- 5 AX=Butanamine* or Methylamphetamine* or Methylenedioxymethamphetamine* or Ethylbarbituric* or Allylglycine* or Amfonelic* or Amiphenazole* or Apomorphine* or Bemegride* or Benzphetamine* or Brucine* or Carphedon* or Cathinone* or Chloramphetamine* or Convulsant* or Cropropamide* or Crotetamide* or Dexamphetamine* or Dexoxadrol* or Dextroamphetamine* or Dimefline* or Dimefline*
- 6 AX=Etamivan* or Ethimizole* or Methylenedioxyamphetamine* or Fencamfamin* or Fenetylline* or Flurothyl* or Fominoben* or Harmaline* or Homococaine* or Hydroxyamphetamine* or Lobeline* or Mazindol* or Meclofenoxate* or Mefexamide* or Methamphetamine* or Methcathinone* or Methylephedrine* or Methylphenidate* or Ethylamphetamine* or Nikethamide* or Norcocaine* or Pemoline* or Pentetrazole* or Phenmetrazine* or Phentermine* or Picrotoxin*
- 7 AX=Pipradol* or Prethcamide* or Prolintane* or Pseudoephedrine* or Pyrovalerone* or Racephedrine* or Strychnine* or Butylbicycloorthobenzoate* or Butylbicyclophosphorothioate* or Tetramethylsuccinimide* or Theodrenaline*
- 8 AX=analeptic* or psychostimulant* or stimulant*
- 9 AX=cannabis or hashish or marihuana or marijua*

- 10 AX=cocaine or crack
- 11 AX=diethylpropion or ephedrine or fenfluramine or methylphenidate or pemoline or phenmetrazine or phendimetrazine or phenylpropanolamine
- 12 AX=heroin or diacetylmorphine or diamorphine or morphin* or morfin* or smack or methadone
- 13 AX=antaxone or dihydroxymorphinan or nalorex or naltrel or naltrexone or revia or trexan or vivitrex
- 14 AX=opiate* or opioid* or opium
- AX=ardinex or codein* or isocodein* or codipertussin or codyl or morfine or methylmorfine or methylmorphine or pentuss or codeine
- AX=dihydrocodeine or codhydrin* or codicontin or cohydrin or dehacodin or didrate or dihydrin or dihydroneopine or drocode or hydrocodeine or hydrocodin or nadein* or napacodin or novicodin or paracodein or paracodin or paramol or parzone or rapacodin or remedacen or tiamon
- AX=abstain* or abstinen* or abus* or addict* or 'drug use' or 'drug user' or 'drug user' or 'drug user' or 'injecting drug' or 'inject drug' or 'injecting drugs' or inject drugs' or intoxicat* or misus* or overdos* or 'illicit use' or withdraw*
- 18 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16
- 19 CS=17 AND 18
- 20 CS=19 OR 1 OR 2

2. HEALTH ECONOMICS AND QUALITY-OF-LIFE SEARCH FILTERS

- a. MEDLINE, EMBASE, PsycINFO, CINAHL Ovid interface
- 1 exp "costs and cost analysis"/ or "health care costs"/
- 2 exp health resource allocation/ or exp health resource utilization/
- 3 exp economics/ or exp economic aspect/ or exp health economics/
- 4 exp value of life/
- 5 (burden adi5 (disease or illness)).tw.
- 6 (cost\$ or economic\$ or expenditure\$ or price\$1 or pricing or pharmacoeconomic\$).tw.
- 7 (budget\$ or fiscal or funding or financial or finance\$).tw.
- 8 (resource adj5 (allocation\$ or utilit\$)).tw.
- 9 or/1-8
- 10 (value adj5 money).tw.
- 11 exp quality of life/
- 12 (quality\$ adj5 (life or survival)).tw.
- 13 (health status or QOL or well being or wellbeing).tw.
- 14 or/9-13

Details of additional searches undertaken to support the development of this guideline are available on request.

APPENDIX 11:

QUALITY CHECKLISTS FOR ECONOMIC STUDIES

1.1 FULL ECONOMIC EVALUATIONS

Autho	pr: Date:			
Title:				
	Study design	Yes	No	NA
1	The research question is stated			
2	The viewpoint(s) of the analysis are clearly stated			
3	The alternatives being compared are relevant			
4	The rationale for choosing the alternative programmes or interventions compared is stated			
5	The alternatives being compared are clearly described			
6	The form of economic evaluation used is justified in relation to the question addressed			
	Data collection			
1	The source of effectiveness data used is stated			
2	Details of the design and results of the effectiveness study are given			
3	The primary outcome measure(s) for the economic evaluation are clearly stated			
4	Methods to value health states and other benefits are stated			
5	Details of the subjects from whom valuations were obtained are given			
6	Indirect costs (if included) are reported separately			
7	Quantities of resources are reported separately from their unit costs			

Appe	naix 11		
8	Methods for the estimation of quantities and unit costs are described		
9	Currency and price data are recorded		
10	Details of currency of price adjustments for inflation or currency conversion are given		
11	Details of any models used are given		
12	The choice of model used and the key parameters on which it is based are justified		
	Analysis and interpretation of results		
1	Time horizon of costs and benefits is stated		
2	The discount rate(s) is stated		
3	The choice of rate(s) is justified		
4	An explanation is given if costs or benefits are not discounted		
5	Details of statistical tests and confidence intervals are given for stochastic data		
6	The approach to sensitivity analysis is given		
7	The choice of variables for sensitivity analysis is given		
8	The ranges over which the variables are varied are stated		
9	Relevant alternatives are compared		
10	Incremental analysis is reported		
11	Major outcomes are presented in a disaggregated as well as aggregated form		
12	The answer to the study question is given		
13	Conclusions follow from the data reported		

Conclusions are accompanied by the appropriate caveats

1.2 PARTIAL ECONOMIC EVALUATIONS

Autho	or: Date:			
Title:				
	Study design	Yes	No	NA
1	The research question is stated			
2	The viewpoint(s) of the analysis is clearly stated and justified			
	Data collection			
1	Details of the subjects from whom valuations were obtained are given			
2	Indirect costs (if included) are reported separately			
3	Quantities of resources are reported separately from their unit costs			
4	Methods for the estimation of quantities and unit costs are described			
5	Currency and price data are recorded			
6	Details of currency of price adjustments for inflation or currency conversion are given			
7	Details of any model used are given			
8	The choice of model used and the key parameters on which it is based are justified			
	Analysis and interpretation of results			
1	Time horizon of costs is stated			
2	The discount rate(s) is stated			

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3	Details of statistical tests and confidence intervals are given for stochastic data		
4	The choice of variables for sensitivity analysis is given		
5	The ranges over which the variables are varied are stated		
6	Appropriate sensitivity analysis is performed		
7	The answer to the study question is given		
8	Conclusions follow from the data reported		
9	Conclusions are accompanied by the appropriate caveats		

APPENDIX 12:

DATA EXTRACTION FORM FOR ECONOMIC STUDIES

Reviewer:	Date of Review:					
Authors:						
Publication Date:						
Title:						
Country:						
Language:						
Economic study design:						
□CEA □C □CBA □C □CUA □CMA						
Modelling:						
□No	□Yes					
Source of data for effect size measure(s):						
☐ Meta-analysis ☐ RCT ☐ Quasi experimental study ☐ Cohort study ☐ Mirror image (before-after) study ☐ Expert opinion						
Comments						
Primary outcome measure(s) (please list):						
Interventions compared (please describe):						
Treatment:						
Comparator:						
Setting (please describe):						

Patient population characteristics (please describe):						
Perspective of analysis:						
☐ Societal ☐ Patient and family ☐ Healthcare system ☐ Healthcare provider ☐ Third party payer	□ Other:					
Time frame of analysis:						
Cost data:						
□ Primary	□Secondary					
If secondary please specify: _						
Costs included:						
Direct medical	Direct non-medical	Lost productivity				
☐ direct treatment ☐ inpatient ☐ outpatient ☐ day care ☐ community health care ☐ medication	□ social care □ social benefits □ travel costs □ caregiver out-of-pocket □ criminal justice □ training of staff	☐ income forgone due to illness☐ income forgone due to death☐ income forgone by caregiver				
Or						
□ staff □ medication □ consumables □ overhead □ capital equipment □ real estate	Others:					
Currency:	Year of costing:					
Was discounting used? ☐ Yes, for benefits and costs	Yes, but only for cos	ts □ No				

	Discount rate used for costs:
	Discount rate used for benefits:
Result(s):	
Comments, limitation	s of the study:
Quality checklist score	(Yes/NA/All):/

APPENDIX 13:

EVIDENCE TABLES FOR ECONOMIC STUDIES

Study ID and country	Intervention details	Study population setting study design – data source	Study type	Costs: description and values outcomes: description and values	Results: cost- effectiveness	Comments internal validity (Yes/No/NA) industry support
Bloom et al., 1993	Three hepatitis B vaccination strategies (no vaccination, universal vaccination, screen and vaccinate)	Different strategies evaluated in four populations (newborns, 10 years old, high-risk population, general adult US) Model:decision tree 30 years time horizon Revaccination every 10 years	effectiveness analysis	Costs: direct medical costs only Perspective of health care payer. For universal vaccination to be cost saving cost per dose should be: US\$7 (general population), US\$13 (adolescent population), US\$34 (newborns)	Cost per life year saved (US\$1,993) Vaccination strategies: -newborns (all): US\$3,066 -newborns (screen and vaccinate): US\$3,332 adolescents (all): US\$13,938 adults (all): US\$54,524 adults (screen and vaccinate): US\$59,101 Vaccination is dominant strategy for adult high-risk populations and neonates	Sensitivity analysis: scenario analysis Costs or savings are sensitive to the costs of hepatitis B vaccine and administration Discounting: cost and outcomes at 5% per year Internal validity: 19/14/2

Study ID Interverse and country details	Intervention details	Study population setting study design – data source	Study type	Costs: description and values outcomes: description and values	Results: cost- effectiveness	Comments internal validity (Yes/No/NA) industry support
Castelnuovo et al., 2006	Treatment: case finding and treatment on progression of hepatitis C virus Comparator: Spontaneous presentation for testing	Former injecting drug users in the UK (average age = 37) Hypothetical cohort (N = 1,000)	Cost- effectiveness analysis	Costs: NHS perspective Systematic offering case-finding to 1,000 is likely to cost £70,000 Outcomes: number of additional people achieving a sustained response from treatment, life years gained (LYG), QALYs	General case: CUA: £16,514/QALY CEA: £20,084/QALY Case-finding for hepatitis C is cost- effective in all sub-populations. It is likely to be more cost-effective if targeted at people whose hepatitis C disease is more advanced.	Discount rate: 6% for costs and 1.5% for health benefits Probabilistic sensitivity analysis: at £30,000/QALY \$> 74% probability to be cost effective At £20,000/ QALY \$> 64% probability to be cost effective Internal validity: 25/8/2
Fals-Stewart et al. 1997	Intervention: BCT Comparator: Individual-based treatment (IBT)	Patients: married or cohabiting substance- misuse males Community	Cost- effectiveness analysis	Costs: Direct costs: cost of providing treatment BCT: Total cost = US\$1,372.72 IBT: Total cost = US\$1,359.94	Each US\$100 spent on BCT produced greater improvements for several indicators of treatment	Perspective: all service providing sectors Currency: US dollars Cost year: 1992

Discounting: not needed Time horizon: 12 months Internal validity: 19/10/6	Perspective: all service providing sectors Currency: US\$ Discounting: not needed Time horizon: 12 months Internal validity: 19/9/8
outcomes (ASI scales, % days of abstinent, consecutive days abstinent after treatment completion)	Annual cost per abstinent client Minimum methadone services: US\$16,845 Counselling plus methadone services: US\$9,804 Enhanced methadone services: US\$9,814
Total cost of substance misuserelated healthcare BCT Baseline: US\$2,617.13 Follow-up: US\$2,362.30 Criminal justice system utilisation costs BCT Baseline: US\$2,832.15 Follow-up: US\$925.80 IBT: US\$3,493.50 Follow-up: US\$2,383.33	Costs: physicians, nurse, counselling (psychological, individual drug, family, group, employment) methadone Cost per person for the first 24 weeks of the programme Minimum methadone services: US\$2,471.09 MMT+counselling: US\$2,315.33
	Cost- effectiveness analysis
Data source of effect size measures and resource use: RCT N = 80 IBT N = 40 BCT N = 40	Patients: methadone- maintained opioid users Inpatient Data source of effect size measures and resource use: RCT: N = 100 Minimum methadone services: N = 31
	Interventions 1st group: MMT with intensive coun- selling 2nd group: MMT plus enhanced coun- selling, medical, and psychoso- cial services
	Kraft <i>et al.</i> , 1997 US

Study ID Interve	Intervention details	Study population setting study design – data source	Study type	Costs: description and values outcomes: description and values	Results: cost- effectiveness	Comments internal validity (Yes/No/NA) industry support	
0280	Comparator: MMT+ minimum counselling	MMT+ counselling: N = 36 MMT+ enhanced counselling, medical and psychosocial services: N = 33		Enhanced methadone services: US\$3,414.03 Primary outcome: Abstinence rates at 12 months' follow-up Minimum methadone services: 29% Counselling + methadone services: 47% Enhanced methadone services: 49%	ICER of minimum services versus counselling plus methadone services: US\$2,289 per additional abstinent client ICER of counselling plus methadone services versus enhanced methadone services US\$22,410 per additional abstinent client		

Sensitivity analysis based on three scenarios reflecting different assumptions Additional cost of extending LDA by 1 week US\$163 (favourable scenario), US\$229 (conservative scenario) and per additional cost of CM per additional negative urine test US\$78 (favourable scenario), US\$130 (conservative scenario), US\$153 (unfavourable scenario) additional cost of extending LOS by 1 week US\$163 (favourable scenario), US\$163 (favourable scenario), US\$254 (conservative scenario), US\$354 (conservative scenario), US\$354 (conservative scenario), US\$354 (conservative scenario)
Incremental cost of CM per additional week of LDA (95% CI): US\$258 (US\$191-401) Incremental cost of CM per additional stimulantnegative urine samples (95% CI): US\$146 (US\$106-269) Incremental cost of CM per additional 1 week extension the LOS in study (95% CI): US\$398 (US\$3398
Costs: Direct costs: counselling, urine and breath sample testing (including the staff cost of administering these tests) and prize system (including the cost of administering the prize system) Average cost per patient (mean, SD): CM US\$730 (\$552) SC US\$292 (\$217) AC = US\$ 438 Significant differences in costs between groups Primary outcome: Longer duration of abstinence (LDA) during treatment (weeks) CM 4.3 (4.6) Usual care 2.6 (3.4) A LDA = 1.7 Secondary outcomes Number of negative urines CM 12.6 (9.0) Usual care 9.6 (8.0)
Cost – effectiveness analysis
Patients who abuse stimulants Community Data source of effect size measures and resource use: RCT: N = 415 CM: N = 209 Usual care: N = 206
Intervention: Prize-based CM plus usual care Comparator: Usual care of psychosocial substance misuse treatment
Olmstead et al., 2007 US

Adults (mean age 33 Cost-utility years) with unknown HIV status in US healthcare settings US communities with 0.05–1.0% prevalence and annual incidence of 0.0084%–0.12%

Sensitivity analysis: scenario testing	Monetary incentives to promote chest x-ray screening are justified if they have a positive impact on adherence Discounting: not needed (healthcare inflation-discount rate) 17.5% of the study population were eligible for TB preventive therapy Funded by NIDA (US) Internal validity:	21/12/2
TB screening and DOPT at a	syringe exchange programme can be a cost-effective intervention for reducing TB among active drug users over a wide range of INH efficacy rates 5-year follow-up: US\$25 incentive → a. increased chest X-ray adherence rate to 50% = US\$170,054 net savings b. increased chest X-ray adherence rate to 100% = US\$170,054 net	US#11+,050
Costs: direct medical, staff fees, supplies, overhead, liver function	tests, chest x-rays, INH preventive therapy, monetary incentives TB infection total cost: US\$10,144.90 TB disease total cost: US\$17,850.16 INH total cost: US\$118,747.36 Outcomes: TB cases averted over a 5-year follow-up under different adherence rates to chest X- ray completion and under a range of INH efficacy rates	
Cost- effectiveness	analysis	
Active drug users with Cost- positive PPD (purified effecti	protein derivative) skin testing or with HIV infection and anergy were evaluated for clinical TB. On-site DOPT with twice weekly INH Syringe-exchange programme in NY, US Study sample: N = 974	
Treatment: TB screening	and on-site DOPT (directly observed preventive ther- apy): twice weekly to receive isoniazid (INH) 900 mg and pyridoxine 50 mg for 26 weeks Comparator: Treating active TB cases that would have occurred in the absence of an intervention	
Perlman et al., 2001	ns	

	setting study design – course the control and values data source and values	
ent effectiveness analysis fect d	Patients: enrolled to outpatient treatment outpatient treatment for cocaine abuse analys Community Data source of effect size measures and resource use: RCT N = 120	atment ouse of effect and
	setting study de data source data source Patients: enrollec outpatient treatm for cocaine abus Community Data source of es size measures an resource use: RCT N = 120	ntions rd ant + low d prize t CM y) STD+ expected ay-out rator: rd care

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	Sensitivity analysis: scenario testing Incentives and enablers to improve completion rates of medical evaluation and preventive therapy
ICER of US\$80 CM versus US\$240 CM: US\$6.9 ICER of US\$240 CM versus STD: \$10.0 Outcome: % samples drug free ICER of US\$80 CM versus STD: \$24.6 ICER of US\$80 CM versus US\$240 CM:	3-year follow-up of 20 cases (95%) averted 10-year follow-up of 30 TB cases (nearly 50%) averted plus 7.6 TB-related deaths
	Costs: Were determined from the perspective of a local TB control programme, inpatient treatment US\$(1998 prices) Total average cost of programme: US\$771,569 Net savings: US\$104,660
	Cost- effectiveness analysis
	Injecting drug users HRTP project based in five methadone mainte- nance clinics in San Francisco, US Study sample: N = 529
	Treatment: Isoniazid 300 mg and pyridoxine 50 mg daily with methadone dosage
	Snyder et al., 1999 US

Comments internal validity (Yes/No/NA) industry support	Discounting: future costs and TB cases averted were discounted at a 3% rate Internal validity:	Perspective: all service providing sectors Currency: US\$ Cost year: 2001 Discounting: not needed Time horizon: 12 months
Comments internal val (Yes/No/NA industry su	Discoucosts a avertec counte Interna 21/9/4	Perspec service sectors Currenc Cost ye Discour needed Time hc months
Results: cost- effectiveness	Net average savings per case prevented: US\$3,724	Cost-benefit ratio: 19:1 Benefit per person: US\$2,804.19 The total cost of preventable read- missions due to AMS: US\$713,372.40
Costs: description and values outcomes: description and values	Outcomes: completion rates of TB skin testing, medical evaluation, preventive therapy, number of active TB cases identified through screening	Costs: Psychiatry: Average cost of 1st admission U\$\$12,410.93 ± U\$\$52,91.19, (mean ± SD) Average cost of 2nd admission U\$\$17,834.31 ± U\$\$24,903.62 Average cost of 3rd admission U\$\$12,902.69 ± U\$\$8,736.57
Study type		Cost-benefit analysis
Study population setting study design – data source		Patients: hospitalised persons with substance use disorders Inpatient Data source of effect size measures and resource use: Retrospective review of all patients admitted to
Intervention details	INH therapy for 6–12 months Comparator: Treating active TB cases that would have occurred in the absence of an intervention	Interventions Addiction medicine services (AMS)-brief interventions + standard care Comparator: Standard care
Study ID Interve		Storer (2003) US

Portsmouth in 2001: N = 444 Brief interventions: N = 186 No brief interventions: N = 258	Portsmouth in 2001: N = 444 Brief interventions:	Average cost of 1st admission	17/8/10
N = 444 Brief inter $N = 186$ $N = 186$ $N = brief in$ $N = 258$	rventions:		
Brief inter $N = 186$ $N = 186$ $N = 186$ $N = 258$ $N = 258$	rventions:	US21,200.93 \pm US$79,846.45$	
N = 186 No brief ir $N = 258$		Average cost of 2nd admission	
No brief ir $N = 258$		US\$23,690.78 ± US\$28,787.04	
N = 258	interventions:	Average cost of 3rd admission	
		US6,904.78 \pm US$26,094.20$	
		The unit cost of AMS-brief interventions: US\$153.70	
		Primary Outcome:	
		Readmission rates	
		With AMS-brief interventions: Internal medicine: 15.4% Psychiatry: 12%	
		Without AMS interventions: Internal medicine: 40% Psychiatry: 10.5%	

11. GLOSSARY

12-step self-help group: A non-profit fellowship of people who meet regularly to help each other remain abstinent. The core of the 12-step programme is a series of 12 stages that include admitting to a drug problem, seeking help, self-appraisal, confidential self-disclosure, making amends (when possible) where harm has been done, achieving a spiritual awakening and supporting other people who misuse drugs who want to recover.

Abstinence: Abstinence-oriented treatments aim to reduce an individual's level of drug use, with the ultimate goal of refraining from use altogether.

Agonist: An agonist is a substance that mimics the actions of a **neurotransmitter** or hormone to produce a response when it binds to a specific receptor in the brain. **Opioid** drugs, for example heroin and **methadone**, are agonists that produce responses such as 'liking', analgesia and respiratory depression.

Alcoholics Anonymous (AA): Alcoholics Anonymous is an informal fellowship of people who, through shared experiences and support for one another, aim to achieve abstinence and help others to recover from alcoholism. The only requirement for membership is a desire to stop misusing alcohol. An international organisation, AA was founded in the US in 1935 and established in the UK in 1947. It was from AA that the **12-step** treatment model originated.

Antagonist: In contrast to the action of an **agonist**, an antagonist, such as **naltrexone**, binds to a specific receptor in the brain but does not activate it. Therefore, if an agonist, for example heroin or **methadone**, is present and activating the receptor, taking naltrexone will counteract the activation, resulting in withdrawal.

Behavioural couples therapy (BCT): Behavioural couples therapy usually involves (a) the person who misuses drugs stating his or her intention not to use drugs each day and his or her partner expressing support for the former's efforts to stay abstinent; (b) teaching more effective communication skills, such as active listening and expressing feelings directly; and (c) helping to increase positive behavioural exchanges between partners by encouraging them to acknowledge pleasing behaviours and engage in shared recreational activities (Fals-Stewart *et al.*, 2002).

Brief intervention: Brief interventions are those with a maximum duration of two sessions, lasting up to an hour each. The main principles include expressing empathy with the service user, not opposing resistance and offering feedback in order to increase the motivation of the service user to make changes to his or her drug use.

Buprenorphine: An analgesic **opioid** substitute used in **maintenance**-oriented treatment, buprenorphine has both **agonist** and **antagonist** properties.

Cannabis: Cannabis is a generic term denoting the various psychoactive preparations of the hemp plant, including marijuana leaves, hashish resin and oil (WHO, 2006). It is the most commonly used illicit drug in the UK.

Case management: Case management is a method of co-coordinating care for people who misuse drugs. An individual worker, the case manager, is responsible for the coordination and, where necessary, provision of this care. Contact with the case manager is usually expected to be on a regular ongoing basis.

Cognitive behavioural therapy (CBT): Cognitive behavioural therapy encompasses a range of behavioural and cognitive behavioural therapies, in part derived from the cognitive behavioural model of affective disorders, in which the patient works collaboratively with a therapist using a shared formulation to achieve specific treatment goals. Such goals may include recognising the impact of behavioural and/or thinking patterns on feeling states and encouraging alternative cognitive and/or behavioural coping skills to reduce the severity of target symptoms and problems. Therapies relevant to the field of drug misuse include standard cognitive behavioural therapy and relapse-prevention cognitive behavioural therapy.

Confidence interval (CI): The range within which the 'true' values (for example, size of effect of an intervention) are expected to lie with a given degree of certainty (for example, 95% or 99%). (Note: confidence intervals represent the probability of random errors, but not systematic errors or bias.)

Contingency management (CM): Contingency management provides a system of incentives and disincentives designed to make continual drug use less attractive and abstinence more attractive (Griffith *et al.*, 2000). The three main methods of providing incentives are voucher-based, whereby vouchers representing monetary values are provided upon receipt of biological samples (usually urine) that are negative for the tested drugs, prize-based (whereby participants receive prize-draw entries upon presentation of a negative biological sample) and privilege-based (whereby participants receive privileges such as take home methadone doses upon presentation of a negative biological sample).

Dependence: Dependence is defined by the WHO as a strong desire or sense of compulsion to take a substance, a difficulty in controlling its use, the presence of a physiological withdrawal state, tolerance of the use of the drug, neglect of alternative pleasures and interests and persistent use of the drug, despite harm to oneself and others (WHO, 2006).

Detoxification: Detoxification is the process by which an individual is withdrawn from the effects of a psychoactive substance. As a clinical procedure, the withdrawal process should be supervised and carried out in a safe and effective manner, such that withdrawal symptoms are minimised. Typically, the individual is clinically intoxicated or already in withdrawal at the outset of detoxification. Detoxification may

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involve the administration of medication, the dose of which is calculated to relieve withdrawal symptoms without inducing intoxication, and is gradually tapered off as the individual recovers.

Drug misuse/problem drug use: Drug misuse is the use of a substance for a purpose not consistent with legal or medical guidelines (WHO, 2006). The ACMD defines problem drug use as a condition that may cause an individual to experience social, psychological, physical or legal problems related to intoxication and/or regular excessive consumption, and/or dependence; any injection drug use also constitutes misuse (ACMD, 1998).

Extended outpatient treatment: Treatment occurs in regularly scheduled sessions, usually totalling fewer than 9 contact hours per week. Examples include weekly or twice-weekly individual therapy, weekly group therapy or a combination of the two in association with participation in self-help groups.

False negative: A test result that fails to detect an effect, condition or drug when it is in fact present.

False positive: A test result that incorrectly shows an effect, condition or drug to be present when it is not.

Family-based intervention: Family-based interventions work jointly with the person who misuses drugs and his or her family members, partner or others from a wider social network (for example, a close friend) to seek reduced drug use or abstinence based on cognitive-behavioural principles.

Harm reduction: Measures aiming to prevent or reduce negative health or other consequences associated with drug misuse, whether to the drug-using individual or to society. Attempts are not necessarily made to reduce the drug use itself.

Incremental cost-effectiveness ratio (ICER): The difference in the mean costs in the population of interest divided by the differences in the main outcomes in the population of interest.

Interpersonal therapy (IPT): A discrete, time limited, structured psychological intervention that focuses on interpersonal issues and where therapist and service user: a) work collaboratively to identify the effects of key problematic areas related to interpersonal conflicts, role transitions, grief and loss, and social skills, and their effects on current drug misuse, feelings states and/or problems; and b) seek to reduce drug misuse problems by learning to cope with or resolve interpersonal problem areas.

Last observation carried forward: A type of data analysis used in clinical trials, often when data is lacking, in which the last results before a subject drops out of the trial are counted as if they occurred at the end of the trial.

Legally coerced (drug) treatment: This requires that the person who misuses drugs enter into treatment as an alternative or adjunct to criminal sanctions (Wild *et al.*, 2002). Such treatment can either be legally ordered by the court or through diversion away from the judicial process, usually following arrest and charge for drug-related and other offences.

Maintenance: In the UK context this refers primarily to the pharmacological maintenance of people who are opioid dependent; that is, prescription of opioid substitutes (**methadone** or **buprenorphine**). This aims to reduce illicit drug use and its consequent harms.

Meta-analysis: The use of statistical techniques to integrate the results of several independent studies.

Methadone: A synthetic, psychoactive **opioid** substitute used in **maintenance**-oriented treatment, particularly heroin dependence. Methadone has **agonist** properties.

Naltrexone: An **antagonist** that blocks the effects of **opioid** drugs on receptors in the brain, naltrexone is used in **maintenance** treatment to prevent detoxified service users from relapsing to opioid use.

Narcotics Anonymous (NA): Narcotics Anonymous is a non-profit fellowship of men and women for whom drug misuse has become a severe problem. Members meet regularly with the aim of helping each other to remain abstinent. The only requirement for membership is a desire to stop misusing drugs. Originating in the US in 1953, the first UK NA meeting was held in 1980. At the core of the NA programme is the **12-step** treatment model, adapted from **Alcoholics Anonymous**.

National Collaborating Centre for Mental Health (NCCMH): One of seven centres established by the National Institute for Health and Clinical Excellence to develop guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales. Established in 2001, the NCCMH is responsible for developing mental health guidelines, and is a partnership between the Royal College of Psychiatrists and the British Psychological Society.

National Institute for Health and Clinical Excellence (NICE): An independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. It provides guidance on three areas of health: clinical practice, public health and health technologies.

National Treatment Agency for Substance Misuse (NTA): The NTA is a special health authority, which was established by the government in 2001. It is tasked with increasing the availability, capacity and effectiveness of treatment for drug misuse in England and embraces user involvement as a core component of its strategy.

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Near-patient testing: This refers to the process of obtaining a biological sample from a service user and using a drug-testing kit to immediately detect the presence of any of a variety of substances (for example, **opioids**, amphetamines, cocaine metabolite, benzodiazepines, methadone and cannabis) on site. This process eliminates the need for external laboratory support and provides rapid results.

Needle and syringe exchange: A service aiming to reduce transmission of blood-borne viruses through the promotion of safer drug injection behaviour, primarily via the distribution of sterile needles, but often also by offering education and other psychosocial interventions.

Neurotransmitter: A chemical messenger (for example, dopamine or noradrenaline) used by nerve cells to transmit nerve impulses from one nerve cell (neuron) to another, or between neurons and other tissues, such as muscles or glands.

Opioid: Opioids refer to a class of psychoactive substances derived from the poppy plant, including opium, morphine and codeine, as well as their semi-synthetic counterparts, including heroin (WHO, UNODC & UNAIDS, 2004). In this guideline, the term 'opioid' is used more broadly to incorporate synthetic compounds (including **methadone**) with similar properties, also commonly known as opioids.

Outreach: Outreach involves targeting high risk and local priority groups. The general aims of outreach work are to: identify and contact hidden populations, refer members of these populations to existing care services, initiate activities aimed at prevention and at demand reduction, and to promote safer sex and safer drug use (European Monitoring Centre for Drugs and Drug Addiction, 1999).

Point abstinence: Point abstinence refers to evidence for the absence of drug use at a particular point in time (for example, at the end of treatment or at 12-month follow-up).

Psychoeducation: Psychoeducation is a programme designed for individuals or groups of people who misuse drugs that combines education about blood-borne viruses with skills training to improve communication, assertiveness and safe sexual and injection risk behaviour. It also provides people with an opportunity to ask questions and receive relevant feedback.

Psychosocial intervention: Any formal, structured psychological or social intervention with assessment, clearly defined treatment plans and treatment goals, and regular reviews (NTA, 2006), as opposed to advice and information, drop-in support or informal keyworking.

Purified protein derivative: The name given to the protein extracted from the bacterium responsible for TB and is used in a skin test for the virus. A small amount of the protein is injected under the skin; if the person has been previously infected, a reaction in the form of a hard red bump will form.

Quality adjusted life years (QALY): A form of utility measure calculated by estimating the total life years gained from a treatment and weighting each year with a quality-of-life score in that year.

Randomised controlled trial (RCT): An experiment in which investigators randomly allocate eligible people into groups to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the different groups. Through randomisation, the groups should be similar in all aspects, apart from the treatment they receive during the study.

Relapse-prevention cognitive behavioural therapy: This differs from standard cognitive behavioural therapy in the emphasis on training drug users to develop skills to identify situations or states where they are most vulnerable to drug use, to avoid high-risk situations, and to use a range of cognitive and behavioural strategies to cope effectively with these situations (Carroll & Onken, 2005).

Relative risk (RR): The ratio of risk in the intervention group to the risk in the control group. The risk (proportion, probability or rate) is the ratio of people with an event in a group to the total in the group. An RR of 1 indicates no difference between comparison groups. For undesirable outcomes, an RR that is less than 1 indicates that the intervention was effective in reducing the risk of that outcome.

Residential rehabilitation programme: Residential rehabilitation centres provide accommodation in a drug-free environment and a range of structured interventions to address drug misuse, including, but not limited to, abstinence-oriented interventions (NTA, 2006). Services vary and are based on a number of different treatment philosophies.

Screening: The systematic application of a test or enquiry to identify individuals at high risk of developing a specific disorder who may benefit from further investigation or preventative action (Peckham & Dezateux, 1998). Routine screening for drug misuse in the UK is largely restricted to criminal justice settings, including police custody and prisons (Matrix Research and Consultancy & NACRO, 2004).

Self-help group: A group of people who misuse drugs meet regularly to provide help and support for one another. The group is typically community-based, peer-led and non-professional.

Sensitivity: A term used to assess **screening** tools, sensitivity refers to the proportion of people with disease who test positive for that disease.

Short-term psychodynamic intervention: A psychological intervention, derived from a psychodynamic/psychoanalytic model in which: a) therapist and patient explore and gain insight into conflicts and how these are represented in current situations and relationships, including the therapy relationship; b) service users are given

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an opportunity to explore feelings and conscious and unconscious conflicts originating in the past, with the technical focus on interpreting and working through conflicts; c) therapy is non-directive and service users are not taught specific skills such as thought monitoring, re-evaluation or problem solving. Treatment typically consists of 16–30 sessions (Leichsenring *et al.*, 2004).

Specificity: A term used to assess **screening** tools, specificity refers to the proportion of people without disease who test negative for that disease.

Standard cognitive behavioural therapy: A discrete, time limited, structured psychological intervention, derived from a cognitive model of drug misuse (Beck *et al.*, 1993). There is an emphasis on identifying and modifying irrational thoughts, managing negative mood and intervening after a lapse to prevent a full-blown relapse (Maude-Griffin, 1998).

Standard deviation (SD): A statistical measure of variability in a population of individuals or in a set of data. While the average measures the expected middle position of a group of numbers, the standard deviation is a way of expressing how different the numbers are from the average. The standard deviation is (approximately) the amount by which the average person's score differs from the average of all scores.

Standardised mean difference (SMD): In a **meta-analysis**, an SMD is a way of combining the results of studies that may have measured the same outcome in different ways, using different scales. Statistically, it is calculated by dividing the weighted average effect size by the pooled standard deviation. The SMD is expressed as a standard value with no units.

Stimulant: Broadly any substances that activate, enhance or increase neural activity (WHO, 2006). Illicit stimulants include cocaine, crack cocaine and methamphetamine. Cocaine is one of the most commonly misused stimulants in the UK; crack cocaine refers to the cocaine alkaloid that has been purified from the other components of cocaine powder, and methamphetamine is one of a group of synthetic substances (amphetamines) with broadly similar properties to cocaine.

Systematic review: Research that summarises the evidence on a clearly formulated question according to a predefined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical **meta-analysis**.

Therapeutic community (TC): The primary goal of therapeutic communities is abstinence from illicit and prescribed drugs, with the residential 'community' acting as the key agent for change. Peer influence is used to help individuals acquire social skills and learn social norms, and so take on an increased level of personal and social responsibility within the unit (Smith *et al.*, 2006).

Weighted mean difference (WMD): A method of meta-analysis used to combine measures on continuous scales, where the mean, standard deviation and sample size in each group are known. The weight given to each study (for example, how much influence each study has on the overall results of the meta-analysis) is determined by the precision of its estimate of effect and, in the statistical software used by the NCCMH, is equal to the inverse of the variance. This method assumes that all of the trials have measured the outcome on the same scale.

Withdrawal symptoms: Withdrawal symptoms ensue when a person who has become tolerant to the effects of a drug stops taking it. Such symptoms typically emerge within 6–12 hours for short-acting opioids such as heroin and about 24–36 hours after the last dose of methadone or buprenorphine, depending on the dose. Withdrawal can also ensue when an opioid **antagonist**, such as **naloxone** or **naltrexone** is taken; this is called precipitated or abrupt withdrawal. Opioid withdrawal symptoms can include pupil dilation, diarrhoea, low mood, irritability, anxiety, insomnia, muscular and abdominal pains, restlessness and 'craving'. In addition, tachycardia, sweating, runny nose, hair standing on end and shivering are generally experienced.

12. REFERENCES

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13. ABBREVIATIONS

AA Alcoholics Anonymous

ACMD Advisory Council on the Misuse of Drugs

AGREE Appraisal of Guidelines for Research and Evaluation Instrument

AIDS autoimmune deficiency syndrome

AMED A bibliographic database produced by the Health Care

Information Service of the British Library

AMS Addiction medicine services
APA American Psychiatric Association

ASAM American Society of Addiction Medicine

ASI Addiction Severity Index

AUDIT Alcohol Use Disorders Identification Test

BCT behavioural couples therapy

CA cost analysis

CA Cocaine Anonymous CBA cost-benefit analysis

CBT cognitive behavioural therapy
CCA cost-consequences analysis
CEA cost-effectiveness analysis

CI confidence interval

CINAHL Cumulative Index to Nursing and Allied Health Literature

CM contingency management CMA cost-minimisation analysis CUA cost-utility analysis

DAST Drug Abuse Screening Test

DATOS Drug Abuse Treatment Outcome Study

DDA Drug Dependents Anonymous

DH Department of Health

DOPT directly observed preventive therapy

DSM Diagnostic and Statistical Manual of Mental Disorders

(versions III-R and IV)

DUDIT Drug Use Disorders Identification Test

EMBASE Excerpta Medica database

FA Families Anonymous

GDG Guideline Development Group

GP general practitioner

GRADE Grading of Recommendations: Assessment, Development

and Evaluation (Working Group)

GRP Guideline Review Panel

HIV human immunodeficiency virus

HMIC Health management and policy database from the Healthcare

Management Information Consortium

HTA Health Technology Assessment

IBT individual-based treatment

ICER incremental cost-effectiveness ratio

INH Isoniazid

IPT interpersonal therapy

K number of studies

LDA Longer duration of abstinence

LOS length of stay
LYG life years gained

MEDLINE Compiled by the US National Library of Medicine and published

on the web by Community of Science, MEDLINE is a source

of life sciences and biomedical bibliographic information

MMT methadone maintenance treatment

n number of participants in a group
N total number of participants
NA Narcotics Anonymous

NACB National Academy of Clinical Biochemistry

NACRO National Association for the Care and Rehabilitation of Offenders

NCCMH National Collaborating Centre for Mental Health NDUDA National Drug Users Development Agency NDTMS National Drug Treatment Monitoring System

NHS National Health Service

NHS EED National Health Service Economic Evaluation Database NICE National Institute for Health and Clinical Excellence

NIDA National Institute on Drug Abuse NSC National Screening Committee NSF National Service Framework

NTA National Treatment Agency for Substance Misuse NTORS National Treatment Outcomes Research Study

OHE HEED Office of Health Economics, Health Economics Evaluation

Database

Abbreviations

p probability

PICO patient, intervention, comparison and outcome

PILOTS An electronic index to the worldwide literature on post-traumatic

stress disorder and other mental-health consequences of exposure

to traumatic events, produced by the US National Center for PTSD

POSIT Problem-Oriented Screening Instrument for Teenagers

PSS Personal Social Services

PsycINFO An abstract (not full text) database of psychological literature from

the 1800s to the present

PTSD post-traumatic stress disorder

QALY quality adjusted life years

RCT randomised controlled trial

RR relative risk

SAS-SR Social Adjustment Scale – Self-Report SCAN Specialist Clinical Addiction Network

SD standard deviation

SIGLE System for Information on Grey Literature in Europe database

SIGN Scottish Intercollegiate Guidelines Network

SMD standardised mean difference

STD standard treatment

TB tuberculosis

TC therapeutic community

TOPS Treatment Outcome Prospective Study

WHO World Health Organisation WMD weighted mean difference